# INCIDENCE OF AFLATOXIN IN THE 1988 CORN CROP DUE TO DROUGHT

## HEARINGS

BEFORE THE

SUBCOMMITTEE ON
WHEAT, SOYBEANS, AND FEED GRAINS

OF THE

COMMITTEE ON AGRICULTURE
HOUSE OF REPRESENTATIVES

ONE HUNDRED FIRST CONGRESS

FIRST AND SECOND SESSIONS

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[1] Resigned from Congress, June 15, 1989.
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# INCIDENCE OF AFLATOXIN IN THE 1988 CORN CROP DUE TO DROUGHT

TUESDAY, APRIL 4, 1989

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON WHEAT, SOYBEANS, AND FEED GRAINS,
COMMITTEE ON AGRICULTURE,
*Washington, DC.*

The subcommittee met, pursuant to call, at 9:30 a.m., in room 1302, Longworth House Office Building, Hon. Dan Glickman (chairman of the subcommittee) presiding.

Present: Representatives Johnson, English, Volkmer, Penny, Sarpalius, Jontz, Marlenee, Roberts, Schuette, and Grandy.

Staff present: Fred J. Clark, associated counsel; Joe Muldoon, assistant counsel; John E. Hogan, minority counsel; Glenda L. Temple, clerk; Greg Frazier, James R. Lyons, Thomas H. Lederer, James A. Davis, and Cliff Humphrey.

## OPENING STATEMENT OF HON. DAN GLICKMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF KANSAS

Mr. GLICKMAN. Good morning. As I said at our first hearing a couple of weeks ago, as members of the subcommittee and I discussed our agenda for the subcommittee this year, one of the first priorities members had was to review the 1988 drought. As the subcommittee was planning the hearing held 2 weeks ago on USDA's implementation of the 1988 Disaster Assistance Act, I became increasingly concerned about reports in the news media about the incidence of aflatoxin in the 1988 corn crop due to drought.

As interest in this subject grew, I determined that we would split the subject off from our general look at issues stemming from last year's drought.

This morning, we will hear from three panels. First, representatives of the Federal Grain Inspection Service; second, a scientific panel; and third, a panel of experts from the grain and food industries.

Parenthetically, I have been informed that there have been a couple of other folks from the scientific community who may be interested in testifying or who have some thoughts to offer in terms of identification of aflatoxin. We will leave this hearing record open for 10 days to allow any additional testimony that people would want to submit.

While I know generally what all witnesses will say and I realize that some may have points of disagreement between them, I be-

lieve it is fair to say that they all share my concern about ensuring that our food supply is safe and that the public is protected.

While aflatoxin is different from some of the recent food safety issues which have arisen lately in that it is a naturally occurring substance, it poses no less of a threat to our food supply. It is incumbent that the Federal Government, in my view, play an active and affirmative role in keeping aflatoxin, as well as other safety and health risks, out of the food chain.

By and large, I believe we have accomplished that goal. That does not mean, however, that more progress cannot be made. That is the focus I hope we can take this morning.

What more can be done to further safeguard our food supply from this danger? Are the testing programs of the Federal Grain Inspection Service or the scientific community wanting for lack of Federal assistance? Are there steps the food and grain industries can take if the Federal Government were to provide additional assistance?

Beside airing this issue, answering these questions and implementing new testing regimes or providing help in the form of Federal funds are the roles that this subcommittee can play in combatting the problem of aflatoxin.

I am looking forward to exploring these issues this morning and finding out how this subcommittee can meet these challenges. I know a great deal of progress has been made in dealing with aflatoxin, but as I noted, recent news accounts raise the legitimate question of whether more needs to be done.

I believe the most productive course for us to pursue is not to duck the issue, but to meet it head-on and proceed responsibly.

I might add that, as I said before, one of our goals was to examine what we are doing in this area, and as I said at the beginning, I believe that by and large we have and are accomplishing our goals of making sure that this naturally occurring fungus, which is a carcinogenic fungus, is not a threat to the public health, but it is worthwhile noting that there is a great deal of interest in both the medical, scientific and producer and agribusiness community to try to meet this challenge, which has been around for an awfully long time, and which is exacerbated by the drought.

I am delighted we have been able to have this hearing to explore some of the options available to us and now I would yield to Mr. Roberts, who is not only a member of this subcommittee, but also is the ranking minority member on the DORFA Subcommittee, with jurisdiction over food safety questions generally.

[The background material from Mr. Glickman appears at the conclusion of the hearing.]

## OPENING STATEMENT OF HON. PAT ROBERTS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF KANSAS

Mr. ROBERTS. I thank the chairman.

Let the record show that two colleagues from wheat country are carrying the banner on behalf of the corn country on the aflatoxin situation.

Mr. Chairman, thank you for calling this hearing. Obviously, aflatoxin is certainly a concern of the corn industry. However, I be-

lieve that the testimony and the information that will be provided by the FGIS will prove to everyone's satisfaction that this is really not a problem. It is a concern, but not a problem.

My notes on this issue indicate that FGIS began taking steps to deal with the aflatoxin concern as far back as 1978. As early as February 1988, as of last year, the agency began the process of finding more efficient and accurate methods of testing for this toxin.

The FGIS records indicate that requests for the test, which is voluntary, have been very significant from the farm level to the export terminals. In fact, all shipments to Mexico, Japan, and Russia are tested as a matter of course.

FGIS can certify that zero percent of the corn shipments they have tested left any U.S. port in excess of 20 parts per million. That is the maximum safe standard, by the way, for human consumption as determined by the FDA.

Even though the aflatoxin standards fall under the Agricultural Marketing Act instead of the Grains Standards Act, it is my understanding that FGIS is working within the spirit of the 1986 grain quality legislation to ensure its testing procedures are consistent with FDA's very strict guidelines.

Furthermore, Mr. Chairman, it is my hope Mr. Miller will elaborate on the memo of understanding that exists between FGIS and the FDA to ensure that when a significant amount of corn or any product is discovered to be in excess of the FDA standards, appropriate steps are taken to protect its reentry into the food-use channel.

I want to commend the FGIS for its work on this issue and really, given the market volatility of last week and the food safety issue that covers everything from apples almost to zebras in this town, it is important we help get the message out to food and beef consumers that our corn supply is safe; it is being monitored and that FGIS is taking steps to improve its ability to maintain the competence of this important commodity.

With that, I will yield back, Mr. Chairman, and look forward to the hearing.

Mr. GLICKMAN. We note the arrival of a corn State member, Mr. Grandy, from Iowa.

Mr. GRANDY. Thank you, Mr. Chairman. To say that Iowa is a corn State is to have a tenacious grasp of the obvious and I appreciate you holding this hearing.

We are fortunate, at least in my section of the State, northwestern, north central Iowa, to have escaped a great part of the aflatoxin problem, but that is not to say that with continued dry weather and lack of rainfall, we may not hold out for long. So I appreciate you conducting this hearing and look forward to the testimony.

Thank you.

Mr. GLICKMAN. Thank you. I have Mr. Marlenee's prepared statement for the record.

[The prepared statement of Mr. Marlenee follows:]

**Statement by Mr. Marlenee**
**Wheat, Soybeans & Feed Grains Subcommittee**
**House Committee on Agriculture**
**Tuesday, April 4, 1989**

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Mr. Chairman:

Thank you for this opportunity to discuss with the Federal Grain Inspection Service and other knowledgable witnesses the subject of possible aflatoxin contamination of some of our domestic grain production due to last summer's severe drought conditions. I think it is highly important that we in Congress not only continue to carefully oversee those who are charged with testing and monitoring the safety of animal and human food ingredients, but that we also fully convey to the consuming public the message that food supplies in this country are probably safer now than at any other time in our history.

It is my understanding that there are actually two relevant standards which are established to measure levels of pesticide residues, or as in this case naturally occurring toxic contaminants, in food products. One of these standards is used to establish a "regulatory" level of legally permissible residue or contamination, and the other is based upon scientific studies and more closely relates to the actual levels which are observed to be causally related to adverse effects on human health.

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Thus, the "regulatory" standard is generally set at levels which are significantly **lower** than those leves which have been actually observed to cause ill effects on human health. I think we do this because we would like to err on the side of safety rather on the other side. And yet, Mr. Chairman, figures which are usually released to the public through the media almost always cite the "regulatory" standard rather than the more scientific level. Thus, in many cases even though a product has been determined to contain more than the permissible FGIS or FDA level of a particular residue or contaminant, the levels may still be well under those levels which have been determined to be causally related to adverse effects on long-term human health.

Perhaps some of our witnesses will want to further address this general topic as we proceed today. But I do think it is terribly important that we all recognize the impact that announcements of possible food contamination has on our economy across-the-board, and especially on those American farmers who produce the food

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ingredients. Reckless statements -- whether made in good faith, or whether made by design -- are a severe disservice to everyone in our society. Public hysteria resulting from such ill-founded warnings about the food we produce and consume can quickly devastate markets both at home and abroad.

Mr. Chairman, with those brief remarks, I look forward to hearing from our witnesses.

Mr. GLICKMAN. Mr. Miller, why don't you come up to the table, and I think you are accompanied by Mr. Tanner and anybody else that you wish to join you. If you would identify the folks for the record, we would appreciate it.

Mr. Miller is the Administrator of the Federal Grain Inspection Service.

**STATEMENT OF W. KIRK MILLER, ADMINISTRATOR, FEDERAL GRAIN INSPECTION SERVICE, U.S. DEPARTMENT OF AGRICULTURE, ACCOMPANIED BY STEVEN TANNER, ASSISTANT TO THE ADMINISTRATOR FOR TECHNOLOGY; DAVID ORR, DEPUTY DIRECTOR, FIELD MANAGEMENT DIVISION; AND JIM BAIR, CONFIDENTIAL ASSISTANT**

Mr. MILLER. Good morning, Mr. Glickman. Good morning, Mr. Roberts, Mr. Penny, and Mr. Grandy.

On behalf of the Federal Grain Inspection Service, I want to thank you for the opportunity to appear here this morning. With me today are Jim Bair, my Confidential Assistant, Steve Tanner, my Assistant for Technology, and David Orr, Deputy Director of our Field Management Division.

Both Mr. Tanner and Mr. Orr were given the responsibility last summer to start proactive thinking in preparation for the consequences of the drought on the 1988 corn crop and whatever consequences that might have for aflatoxin.

I would like to present a brief statement and then answer questions for the committee.

We appreciate the opportunity to discuss the Federal Grain Inspection Service's role as a service organization providing official aflatoxin testing for producers, shippers and domestic and foreign processors.

Much concern has developed recently regarding the specific mycotoxin known as aflatoxin. Aflatoxin is produced by two types of mold known as *Aspergillus flavus* and *Aspergillus parasiticus*. The *Aspergillus flavus* is very common and widespread in nature and is more likely to occur in corn when it is grown under stressful conditions such as drought. It can occur in soil, decaying vegetation, hay and grains undergoing microbiological deterioration. It can invade all types of organic substrates whenever and wherever the conditions are favorable for its growth.

Favorable conditions include high moisture content and high temperature. At least 13 different types of aflatoxin are produced in nature. Aflatoxin B1 has been regarded as the most toxic.

For years, FGIS has offered aflatoxin testing services under the auspices of the Agricultural Marketing Act of 1946. The service is provided on an optional, user-fee basis. FGIS provides an ultraviolet light screening test at export locations, but plans to replace this technique during the latter part of 1989.

In addition, we offer two more definitive types of analysis, the Holaday-Velasco minicolumn and the CB thin-layer chromatography techniques. Both of these methods are approved by the Association of Official Analytical Chemists.

The minicolumn is standardized at a specific detection threshold and provides a positive or a negative reading measured against a

20-parts-per-billion standard. It requires approximately 45 minutes to perform the analysis. FGIS charges $22.40 per hour for on-line inspection and $18.90 for individual samples for the aflatoxin testing program.

The thin-layer chromatography analysis provides quantitative results in actual parts per billion. It requires 3 to 4 hours to complete the analysis and FGIS charges $44 for this TLC analysis.

The minicolumn and thin-layer chromatography techniques are performed in laboratories by highly trained technicians. While these techniques are sophisticated, they have shortcomings in that they are slow and involve the use of hazardous chemicals. To implement a more rapid test, FGIS began in February 1988 to evaluate new technologies.

Of particular interest is an analysis which is referred to by the ELISA, acronym ELISA, which is enzyme-linked immunosorbent assay. This biotechnology-based diagnostic technique is similar to many diagnostic techniques used in clinical laboratories. I should add that there are other methodologies, also.

Results can be obtained in several minutes at a reasonable cost. It is highly rewarding to FGIS, and to me personally, to bring technology from other industries to the business of grain inspection, in addition to helping FGIS provide better service to its customers, who are the producers, shippers and processors. Our Research and Development Branch, located at the FGIS Quality Assurance and Research Center in Kansas City, is evaluating the performance data of six various tests and we expect to announce the results of the evaluation in May.

The drought conditions in 1988, particularly in certain sections of the Corn Belt, enhanced the potential for increasing the presence of *Aspergillus flavus* mold that produces aflatoxin. To provide maximum service to producers, FGIS briefed the Agricultural Stabilization and Conservation Service and the Federal Crop Insurance Corporation regarding available analytical services. This was done in approximately August of last year.

We submitted a briefing paper to the USDA Drought Task Force to alert them to the potential problem. This was done in July 1988.

As the drought continued, we expanded the availability of our aflatoxin testing service to meet the expected high demand for service. We increased the number of FGIS laboratories with aflatoxin testing capabilities and secured the use of the Agricultural Marketing Services Laboratory in Medill, Oklahoma, to help test samples if it was necessary during peak demand.

By using overnight mail services, we have been able to analyze samples from interior locations nationwide and provide next-day service in most cases.

The Food and Drug Administration, which is the regulatory agency with surveillance and enforcement responsibility for aflatoxin and other deleterious substances in the food system, issued updated guidelines for safe usage of corn contaminated with aflatoxin.

Depending on the intended end-use, FDA has the following four guidelines that are deemed safe:

Zero to 20 parts per billion; the corn contaminated with zero to 20 parts per billion aflatoxin can be used for all uses, including unknown destinations;

If it has 21 to 100 parts per billion, the corn can be used for breeding cattle and swine, mature poultry, finishing swine, finishing beef cattle;

If it has 101 to 200 parts per billion, then it can be used for finishing swine and finishing beef cattle; and

201 to 300 parts per billion is restricted just for finishing beef cattle.

In response to the new FDA guidelines and increased demand for service, FGIS modified the minicolumn procedure for aflatoxin to correlate to each of the FDA-guideline levels.

Through a memorandum of understanding, the FDA and FGIS cooperate in the detection and control of grains and oilseeds adulterated, infested or contaminated with poisonous or deleterious substances, including aflatoxin. If officially sampled grain is tested by FGIS and found to contain aflatoxin in excess of 20 parts per billion, we alert the appropriate FDA district office.

FDA provides follow-up action, which includes permission to transport and use the corn if adequate documentation is supplied to verify the intended use of the corn. Other options include seizure by FDA or voluntary destruction.

At the onset of the 1988 corn harvest, FGIS determined that while we regularly provide aflatoxin testing services for foreign buyers, extra monitoring was necessary to help ensure buyers of the wholesomeness of U.S. corn. On October 24, 1988, FGIS field offices began to inspect and monitor for aflatoxin for all corn shipments destined for Japan, the Soviet Union and Mexico. These countries are important customers of U.S. corn and they normally import large quantities of the corn.

During the 1987–88 crop year, for example, those countries purchased approximately 24 million metric tons of U.S. corn. All export corn shipments that FGIS certified for aflatoxin were at or below the FDA guidelines of 20 parts per billion.

In calendar year, 1987, FGIS conducted aflatoxin analyses on 44 percent of the total corn tonnage exported that year. This compares to 55 percent in 1988. Thus far, in 1989, we have tested 75 percent, or 9,184,415 metric tons of exported corn for aflatoxin.

Again, I would like to reiterate that in 1987, it was 44 percent of the corn that was tested for aflatoxin; in 1988, it was 55 percent; and in 1989, it was 75 percent.

Again, of the 1989 export corn tonnage tested for aflatoxin, we have not issued an aflatoxin certificate that exceeds the 20-part-per-billion guideline established by FDA. The results for export corn shipments, however, do not represent a profile of U.S.-corn quality nationwide.

Through its aflatoxin testing services, I believe that FGIS provides producers, shippers, and processors with information which enables the marketplace to operate efficiently and to channel the corn with varying levels of aflatoxin into the safest and most appropriate end uses.

Mr. Chairman, this concludes my statement and I will be glad to respond to any questions that you or other members of the committee may have.

[The prepared statement of Mr. Miller appears at the conclusion of the hearing.]

Mr. GLICKMAN. Let me, first of all, thank you, Mr. Miller. I want to go over this report.

You say that 75 percent of the corn that is exported for 1989 has been tested?

Mr. MILLER. That is correct.

Mr. GLICKMAN. None has exceeded the 20-parts-per-billion guideline.

Mr. MILLER. That is correct.

Mr. GLICKMAN. That indicates, at least in terms of the export market, we are doing a good job of keeping aflatoxin out of that corn, right, and our customers ought to know that we are, in fact, selling them uncontaminated corn.

Mr. MILLER. That is correct, Mr. Chairman.

Mr. GLICKMAN. What does this next sentence mean? "The results for export corn shipments, however, do not represent a profile of U.S.-corn quality nationwide"? That is the following sentence to your statement. You indicate that everything is fine on the export market.

Then the last sentence on that page 5 in that paragraph is that—seems to imply that this doesn't mean that the domestic market is so well protected.

I wonder if you could explain that.

Mr. MILLER. Mr. Glickman, as you know quite well, last year, the United States was affected by the drought in different regions; more severely in some regions than in other regions. Places like eastern Iowa and parts of Illinois were impacted severely by the drought and consequently, some of the corn crop in that localized area was impacted fairly severely by aflatoxin.

The State health departments in both the State of Iowa and the State of Illinois rigorously inspected the corn in those States to protect the consumers and general public from an aflatoxin contamination problem and we commend the officials in both States for the excellent job they did.

Other States monitored the crop and found a less severe problem, but in those two States, there was an incidence—in a few cases, some severe infestations of aflatoxin. However, because of the monitoring that was done by the States, that crop was routed into either industrial or alternative uses that assured the safety of the human food supply.

Mr. GLICKMAN. Still, I want to know what that sentence means. What that sentence essentially means is that you have tested the exported corn, but the domestic corn has not been fully tested? The only thing I am trying to question here is it says, "The results for export corn shipments, however, do not represent a profile of U.S. corn quality nationwide."

I just want to get for the record what that statement means because I don't want the impression to go out here that our export corn is great, but our domestic corn is bad. I am just trying to get you to clarify what that statement means.

Mr. MILLER. The agency has not tested all the corn in the domestic market, but I think that leaves an unfair impression on the record and I think it requires expansion and clarification.

Most of the domestic corn buyers, whether it be a corn miller or a corn refiner or a feed manufacturer, have the corn tested for the presence of aflatoxin. We would not have that information available to us and that is the reason why we are vague in that area.

I don't want to leave the impression that the corn goes untested. Because of product liability, corn refiners and corn millers obviously will test the crop very carefully to assure that there is not a contamination problem.

Mr. GLICKMAN. In terms of the levels of aflatoxin because of the drought, you talked about a couple of States which have monitoring programs and ongoing concerns. Iowa was one of them. Are you seeing an increase in incidence of aflatoxin in the 1988 corn crop over and above what it would have been in 1987, 1986, 1985 and previous years?

Mr. MILLER. Mr. Glickman, I don't think there is any question about that. There is more aflatoxin out there because of the drought last year.

Normally, we would expect that the Corn Belt would produce corn that is very low in occurrence of aflatoxin or certainly at much less levels than what we have experienced this year.

Mr. GLICKMAN. What about other crops besides corn? I understand that aflatoxin can contaminate just about any crop.

Mr. MILLER. That is true; it could. We have had some requests this year for monitoring and testing some export shipments for other commodities for aflatoxin, as well as the corn. We do provide that service upon request.

Mr. GLICKMAN. But do you see any increase in aflatoxin in other crops besides corn?

Mr. MILLER. I am not sure that we have a good reference point to relate to previous years for sorghum or wheat or other crops. It is such a rare occurrence that we would have a request for this type of testing for these other grains because they just aren't commonly impacted by it.

This year, we did have requests because of the media hysteria that was generated on the corn crop. This spilled over and applied to some of the other grains. Again, we don't have a good data reference point to make a comparison from this year to last year, for instance.

Mr. GLICKMAN. It is still fundamentally a corn issue, though? It is not fundamentally an other-grains issue?

Mr. MILLER. That is correct. Corn is the best host for the *Aspergillus flavus* fungus.

Mr. GLICKMAN. The Wall Street Journal has run some stories on this issue and one of their allegations was that the chances of aflatoxin being caught are very slim domestically. There are not enough tests nor enough manpower to actually do what needs to be done.

Could you comment on that?

Mr. MILLER. I would be glad to comment on that.

I think that that reflects an attitude that the only people who can test for aflatoxin are Federal regulators. I don't personally sup-

port the theory that they are the only ones who can possibly check for aflatoxin.

Companies all over this country, including country elevator operators, processors, bakeries or end-product manufacturers, are testing constantly for all types of deleterious substances and that information is available to the Food and Drug Administration. I think that the Wall Street Journal article ignores the testing that takes place as a normal course of everyday business in this country.

Because of product liability exposure, no American manufacturer is going to wantonly, willfully ignore the responsibilities he has for protecting the human food supply.

Mr. GLICKMAN. Let me ask you this: What happens to loads of corn which are rejected? Let's say that a farmer brings grain to the country elevator, corn, that is determined to have an excessive level of aflatoxin contamination?

What does the farmer then do in that circumstance? Can that grain be tracked and will the ASCS Office make a disaster payment under those circumstances?

Mr. MILLER. Your question is really a two-part question.

The first part, relative to what happens to the corn—there are several options available to the farmer. One, he can destroy the corn and take the disaster payment provision; or, he can, depending upon the level of aflatoxin contamination in the corn, route it to an alternative use.

Again, if it is below 300 parts per billion, it could still be safely used for some livestock feed. If it exceeds 300 parts per billion, chances are it will be destroyed or possibly processed into ethanol.

Mr. GLICKMAN. There is no way, though, really, for the Government to monitor that grain, is there?

Mr. MILLER. Not really——

Mr. GLICKMAN. Once rejected?

Mr. MILLER. Not really because when the farmers are delivering to the country elevator, for the most part, that is a private transaction without Government inspection. It is negotiated between the buyer and the seller on the basis of tests provided by the local elevator. In most cases, the local government, whether it be State government or Federal Government, would not be aware of the results of these tests.

Mr. MARLENEE. Will the chairman yield?

Mr. GLICKMAN. Yes, I would be glad to yield.

Mr. MARLENEE. I thank the chairman for yielding.

Along this line about the safety of the tests and the opportunity to detect, have there been any cases that you know of, documented cases where humans have been affected by this disease?

Mr. MILLER. First of all, Mr. Marlenee, I am not really qualified to answer that question, but I am not aware of any.

Mr. MARLENEE. In your opinion, do you know of any?

Mr. MILLER. I am not aware of any, sir, but I am not really qualified to——

Mr. MARLENEE. So with our tests and our back-up systems that we have, you know of no cases where the disease escaped detection and humans were adversely affected?

Mr. MILLER. No, sir, I am not.

Mr. MARLENEE. I thank the chairman.

Mr. GLICKMAN. Thank you.

Let me ask you a question again. I want to go back to the situation where a farmer takes a load of corn to the elevator and it is rejected. As you said, there are not really very good ways to follow that grain through the process.

What if there were an ongoing compensation program, as there is for milk right now, which has been utilized in years past for aflatoxin-contaminated milk, would that help keep grain with aflatoxin out of commerce, and would you favor that kind of program?

Mr. MILLER. Mr. Glickman, I think that it is difficult for anybody to oppose anything that is going to ensure the safety of the human food supply. However, you have to look at it and weigh the cost for that particular action versus the benefit that would be derived from it.

Again, I think that that type of a solution to the problem presupposes that this is a more severe problem, an ongoing problem, than what I believe that it is. I think that this was an isolated problem. It is atypical. We would normally not expect this type of contamination problem in the corn crop in the Midwest, and therefore, that type of solution might be a major overkill for what is an isolated problem.

We do have alternative uses that we can route this corn to without the Government getting involved in expensive compensation programs.

Mr. GLICKMAN. One final question from me. The question of mandatory testing. I do not believe that there is a system of mandatory testing at the elevator level. I am not sure exactly what the Government's requirements are for testing for aflatoxin.

Would you favor any changes in not so much the technology, but how we test for aflatoxin, and including whether there ought to be a mandatory testing system?

Mr. MILLER. This year, the ASCS imposed a requirement on producers that the corn crop going into the Government loan program be tested for aflatoxin. I think that caught the major portion of the U.S. corn crop. I don't have the data available to indicate what portion of the U.S. corn crop might have escaped that testing requirement, but I would estimate it was a very, very small percentage.

Mr. GLICKMAN. You did have mandatory testing, then, for any corn crop that was going into the program?

Mr. MILLER. That is correct.

I would like to expand on that just to say that in regard to the ASCS involvement—I am not here to defend them, but they took very important proactive actions last summer to require testing of all the commodities purchased for the school lunch program and for export under the public assistance programs.

More than 350 million pounds of corn or processed corn commodities have been tested under that program. They have imposed that requirement on all the corn and corn-based products.

Mr. GLICKMAN. OK. I have no further questions. I appreciate your testimony. There will be some testimony afterwards that talks about the perception—at least there is a great gravity to the aflatoxin problem because of the extraordinary carcinogenic nature of the fungus, but at least based on your testimony today, in terms of

the crop out there and the ability to determine aflatoxin, your testimony is that we are on top of the problem.

Mr. MILLER. I believe we are, sir.

Mr. GLICKMAN. Thank you.

Mr. Marlenee.

Mr. MARLENEE. I will just take one brief moment.

Aren't most toxins, naturally occurring toxins, in food rather prevalent throughout the food chain? It is just a question of how much toxin that we have in the food, naturally occurring foods, Dr. Miller?

Mr. MILLER. We would have to agree to that, Mr. Marlenee, yes.

Mr. MARLENEE. Second, and I think my last question—and I ask unanimous consent, first of all, Mr. Chairman, to enter into the record my opening statement.

Mr. GLICKMAN. The gentleman will be granted that request and his statement will appear at the beginning, right after my statement.

Mr. MARLENEE. I thank the chairman.

I think I am just going to pass at this time. I am going to yield to my other colleagues who were here before I was. I was detained this morning.

Mr. GLICKMAN. Thank you.

Mr. Johnson.

Mr. JOHNSON. Thank you, Mr. Chairman.

The concern about aflatoxin contamination is based, as the gentleman has indicated, on its ability to cause cancer, liver cancer in particular, but also kidney, colon and bone cancer. One of the concerns I would have, in any event, is that by our FDA guidelines, it is deemed safe to have zero—anywhere up to 20 parts per billion aflatoxin for any purpose, human consumption; up to 300 parts per billion for—the highest possible amount, for feeding—finishing beef cattle.

I am advised that the European Community, as well as Japan, has lowered their standard to 5 parts per billion, about one-fourth of what the United States permits. Has there been any evaluation of—and I appreciate this may be better directed to someone else, but I wonder if you would care to elaborate on the—on any review that has taken place on the permitted parts per billion that we have decided to allow?

Mr. MILLER. Mr. Johnson, you are correct in that there are discussions taking place in countries around the world about what are acceptable levels for aflatoxin. I should point out that our level is set by our Food and Drug Administration, operated under the Public Health Service.

We provide testing services for other countries on contract. For instance, the Japanese have indicated that they would like to have shipments containing not more than 10 parts per billion and we have the capability to test and certify at that level. The Food and Drug Administration policy of 20 parts per billion for human consumption is an acceptable risk level.

We certainly aren't in the business in the Federal Grain Inspection Service to set those levels.

Mr. JOHNSON. Following on the chairman's question, it has been not your belief that the fact that the only place we have a truly

comprehensive testing is with the export market. That fact does not contribute towards a greater likelihood that aflatoxin-contaminated corn would flow into the domestic market.

Mr. MILLER. I think that is very true, Mr. Johnson. I would respond to you similar to the way I responded to Mr. Glickman, in that most domestic processors have a zero tolerance for aflatoxin. Most processors have very elaborate quality-control laboratories in which they test extensively for deleterious substances, such as aflatoxin.

Mr. JOHNSON. Very good.

I pass on the remainder, then, and pass it back to you, Mr. Chairman.

Mr. GLICKMAN. Mr. Roberts.

Mr. ROBERTS. Thank you, Mr. Chairman.

I think it is obvious that food safety is a front-burner issue. That is in part why we are having these hearings; why we are having all the attention here, and also from the full room.

Your testimony discusses your cooperation with the FDA to protect the food chain in that regard. Could you really go over again your role and that of FDA relative to the discovery and subsequent steps taken to isolate any corn that may be contaminated?

Mr. MILLER. I would be happy to do that, Mr. Roberts.

First of all, the Food and Drug Administration has the primary responsibility for regulating the safety of the U.S. food supply.

Mr. ROBERTS. So the question by Mr. Johnson could be answered by Dr. Young with the FDA?

Mr. MILLER. That is correct.

In addition, because of the presence of Federal Grain Inspection Service inspectors in the inspection points across the country, we have a Memorandum of Understanding that was entered into many years ago, but updated on April 9, 1986. That agreement lays out the conditions under which the Food and Drug Administration and the Federal Grain Inspection Service cooperate on providing shared results to each other. It outlines very specifically what steps will be taken by FGIS under certain conditions if we find a violative lot of contaminated grain, and also spells out very clearly what the Food and Drug Administration will do.

We made copies of that material available to the committee staff yesterday.

Mr. ROBERTS. So you have the structure, you think, to deal with this problem in a cooperative fashion?

Mr. MILLER. Yes, we do. We met with the Food and Drug Administration last October to review the Memorandum of Understanding to make sure that the agreement was current and appropriate, given the conditions of the crop last fall.

We feel that we had met with them in a proactive manner to discuss the validity of the Memorandum of Understanding and found it to be very adequate.

Mr. ROBERTS. I want to go back to the question by my colleague from Montana. I said in my opening statement that there was concern. There always is concern in regard to a problem of this nature, but there was no problem. There is a concern, obviously, because of the drought and because of what will happen from time

to time when we have these conditions, and in that regard, I want to be more specific.

How many official reports of aflatoxin poisoning have occurred in the past year? Mr. Miller, if you don't have that information, would that come under FDA and Dr. Young as well?

Mr. MILLER. Yes, it would.

I am not aware of any.

Mr. ROBERTS. I happen to be meeting with him this afternoon at 4:30 on the whole food safety issue, so I can at least ask him that question.

I was going to ask in the last 10 years.

Mr. MILLER. The Public Health Service would probably have that information, but we don't have that information. I am not aware of any personally.

Mr. ROBERTS. I would just add, Mr. Chairman, that I do have a concern about this, but I think it is a lot like we have seen in other cases with the food safety issues.

We had a hearing in the DORFA Subcommittee to point out the progress we have made in the Federal Insecticide, Fungicide, and Rodenticide Act, the fact that we are going to speed up the scientific review process; we are going to have a negligible-risk bill, if you will, to protect the consumer on all sides, the Agriculture Committee and those of us in agriculture are stepping up to the food safety problem.

I know it is a concern of everybody's. It has been on the front pages of our national magazines and our newspapers and even you have movie stars scrubbing up broccoli with detergent. As a matter of fact, if you eat that, it is far worse for you with the detergent on it than you would in terms of any natural occurring substance or any pesticide, but be that as it may, I really want to emphasize that while we have a concern here that you are stepping up to the problem, we have no official evidence of any widespread safety concern here.

So, with that, I will yield back. Thank you.

Mr. GLICKMAN. Mr. Volkmer.

Mr. VOLKMER. Thank you very much. I am sorry, too, I was unable to hear your full testimony. I have reviewed it and I would like to ask if you can tell me whether aflatoxin is recognizable on corn with the human eye?

Mr. MILLER. Not with the naked eye. There is a method for using an ultraviolet light to screen the corn and it will floresce a bright greenish-yellow color.

Mr. VOLKMER. In other words, a farmer himself has no way of knowing whether there is aflatoxin.

Mr. MILLER. Let me say that there are some commercial vendors that have developed some diagnostic kits that are in early stages of marketing. These kits have only been in the marketplace for the last 2 or 3 years. They are becoming available even at the producer level and show tremendous promise.

We are very excited about the prospect for using these kits at the farm level so that farmers themselves will have a mechanism for determining whether they have an aflatoxin problem. I would say that most farmers are not aware of this yet. They are just becoming aware of it and the kits are becoming more widespread and

available, but we see this as a tremendous opportunity for farmers to test their crop themselves.

Mr. VOLKMER. We have quite a few farmers out here who feed their own grain to their own livestock. What we have addressed here so far, as I review your testimony, has been grain that has been for sale, either for livestock feed, poultry feed or for human consumption, export, what have you, but you haven't addressed the problem, have you, of own use?

Mr. MILLER. We offer an optional service to any farmer who would like to submit his corn to the Federal Grain Inspection Service. We would be happy to test their corn for a fee to determine whether or not aflatoxin is present.

We are hopeful that when we complete the evaluation of the six diagnostic kits that we are currently testing, that we will be able to make this information widely known to farmers and that they will also be able to go to their local official inspection agencies and get aflatoxin analyses at the local elevator or wherever.

Mr. VOLKMER. But we still have quite a bit of this corn in storage right now?

Mr. MILLER. That is correct.

Mr. VOLKMER. The other question I have, and you may not be the person to answer it—we will have later witnesses, I think, who will probably answer it also, but if you do know the answer, I would like to hear it because I am just curious more than anything else.

How long has aflatoxin been around as far as human experience—in other words, that we know of? When was it first discovered? Does anybody know?

Mr. MILLER. About 1960 or 1961.

Mr. VOLKMER. It wasn't discovered until that time?

Mr. MILLER. It was in the early 1960's.

Mr. VOLKMER. Anybody know why, what brought it about? We have been raising grains in this world for long periods of time.

Mr. MILLER. We understand there was a feeding trial for turkeys that triggered the original diagnosis or identification of aflatoxin. That was what triggered the first awareness to aflatoxin.

I think that one of the subsequent witnesses is well-qualified to answer that.

Mr. VOLKMER. Right. They probably would know better. I will wait.

Thank you, Mr. Chairman.

Mr. GLICKMAN. I just want to follow up on one of Mr. Volkmer's questions, though, in terms of corn that is fed on-farm, corn that is in storage. In terms of the percentages of corn which is tested, domestically tested, for aflatoxin, as we talked about the corn that goes into the program, as you said, it is tested as it goes to the elevator.

In your judgment, what percent of the corn is tested that is used domestically and what percent is not tested?

Mr. MILLER. Mr. Glickman, I can't offer an opinion on that. I really don't know.

Mr. GLICKMAN But following up on Mr. Volkmer's question, it would be a fair statement to assume that there is a lot of corn that is going untested, then—if it is being fed on-farm?

Mr. MILLER. I would say that is true, yes.

Mr. GLICKMAN. Thank you.

Mr. Grandy.

Mr. GRANDY. Thank you, Mr. Chairman.

Mr. Miller, let me begin by thanking you for saluting the State of Iowa in their attempts to arrest and contain the aflatoxin problem. A lot of that credit does go to the Iowa Corn Growers Association, who convened a task force, as you know, in August of last year.

Mr. Chairman, I would ask unanimous consent to include a copy of the Iowa Corn Growers' Green Sheet—which is actually white—probably make little difference in this hearing—which contains, I think, a very good discussion of recommendations and methodology, for the hearing.

Mr. GLICKMAN. Without objection.

[The material follows:]

# THE GREEN SHEET

THE NEWSLETTER OF THE IOWA CORN GROWERS ASSOCIATION



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# SPECIAL HARVEST ISSUE

This special issue has been put together to inform you of general quality considerations and suggested guidelines on handling and storing drought stressed corn as harvest progresses. What follows is a compilation of information from Iowa State University, marketers, the Iowa Department of Agriculture and the ICGA.

## DROUGHT STRESSED CORN SUSCEPTIBILITY TO MOLDS AND AFLATOXIN

This year's above normal temperatures and lack of rainfall may have created in some Iowa corn fields mold growth in standing corn. An above normal amount of molds or field fungi have been seen in standing corn this fall. These are generally called kernel rot or ear rot. One other more serious field fungi is commonly referred to as Aspergillus or aflatoxin.

Aflatoxin is a carcinogenic by-product of the Aspergillus flavus mold and is generally seen in southern U.S. corn. Normally very little, if any, midwest corn contains aflatoxin. Aflatoxin risk increases with the severity of stress and heat. Heat conditions were favorable for mold growth in August throughout the corn belt.

At this point, it's hard to tell what the extent might be. There will probably be areas where high levels of aflatoxin could be produced and producers should be alert to the possibility of its existence. Knowing what aflatoxin is, what it does and how to manage it will be key in corn producers and marketers handling any serious levels found in corn. Most situations of aflatoxin can be managed properly through rational management situations.

Areas and fields where yields have been cut 30-40 percent or more have the greatest risk of having high aflatoxin concentrations. However, past experience shows that even in the most susceptible areas, there will be corn with little or no aflatoxin. The erratic nature of the problem makes a general estimate of aflatoxin content impossible. Reports of statistically inaccurate surveys of aflatoxin presence may tend to "inflate" the situation beyond its real status.

## AFLATOXIN CAN POSE HEALTH RISK

Most fungi are harmless and pose little health risk. A few produce potent chemicals called mycotoxins which in small amounts can affect the health of livestock and humans. Aflatoxin is a carcinogen caused by the aspergillus flavus mold. For that reason the Food and Drug Administration (FDA) has established a maximum level of 20 parts per billion (ppb) of contamination for corn moving through commercial interstate markets. In 1983, aflatoxin was found in various parts of the upper midwest and some corn shipments were affected. In 1983 the FDA waived the 20 ppb level and established a 100 ppb level to facilitate interstate commerce. The FDA's higher level presented no serious health threat to the general public.

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**WHERE MOLDS AND AFLATOXIN COME FROM**

Molds or fungi can get their start while the corn is still in the field. Usually damage caused in the field can be detected by routine inspection and does not continue to increase in storage if grain is stored at proper moisture content and temperature. If grain is not properly stored the tiny mold spores can increase rapidly, leading to higher aflatoxin levels and significant problems in the end use of the corn.

**HOW TO DETERMINE IF YOU HAVE AFLATOXIN**

Examination of grain with a black light will give an indication of contamination with aflatoxin, but this method is strictly a screening test and does not give an indication of the level of contamination. If the potential for aflatoxin exists, the mold will glow a bright green-yellow. Proper interpretation of color under the blacklight is very important because many compounds other than aflatoxin may glow. However, not all samples that show positive under the blacklight will contain aflatoxin. Black light positives can be confirmed with more sophisticated tests such as an antibody quick-card or a simple chemical extraction (minicolumn) or by laboratory chromatography analysis. All of these tests have higher costs and time requirements to perform.

The importance of an accurate and representative sample cannot be stressed enough. The weight represented by 20 ppb is equivalent to only 20 kernels in a rail car (1500 bushels.) Because aflatoxin is not evenly distributed in all kernels, the collection of a large sample (preferably 10 lbs and certainly no smaller than 5 lbs) is essential. The entire sample should be examined under a black light. Coarse grinding and mixing of the kernels needs to be done before minicolumn or chromatography tests should be done.

**RECOMMENDED HARVEST PROCEDURE FOR MOLDS AND SUSPECTED AFLATOXIN CORN**

If corn is obviously moldy in the field, harvest it promptly. Clean the corn before putting into storage. Do not mix mold or known aflatoxin-contaminated corn with clean corn.

Field molded corn above 20 percent moisture should not be low temperature dried. This slow drying process can allow the aflatoxin contamination to get worse. On the other hand, drought stressed corn is brittle and prone to breakage. Grain temperatures in excess of 149 degrees(F) will aggravate the breakage problem. Grain management in stress conditions is a tradeoff between breakage potential and mold damage. Dry the shelled corn to at least 15 percent moisture as rapidly as possible and no longer than 24-48 hours after harvest. Safe, long-term storage can be achieved at a uniform moisture content of 13 percent moisture.

Cool the grain after drying and maintain dry storage conditions. Where possible, continue cooling until grain temperature reaches 36-41 degrees fahrenheit.

Holding wet grain, even for short periods (overnight in a wagon) is not recommended since considerable amounts of aflatoxin can be produced in a short period of time. Aflatoxin concentrations can increase even without a noticeable change in the visual moldiness of the kernel.

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RECOMMENDED HARVEST PROCEDURE FOR MOLDS AND SUSPECTED AFLATOXIN CORN . . . continued

Bins should be thoroughly cleaned before storage to remove dirt, dust and other foreign material. All storage should be water tight and free from insects and rodents. Continued periodic aeration and probing for "hot spots" at intervals of one to four weeks throughout the storage period is essential to preserve the quality of the corn put in storage.

LIMITED METHODS TO REDUCE CONTAMINATION

There are no fungicides currently labeled for use on stored corn in Iowa to prevent mold growth. There are no practical approved methods for detoxifying large amounts of contaminated corn. Dryer heat will not break down mycotoxins (mold toxins.) Rigorous cleaning will remove broken particles which are more susceptible to mold invasion. This may lower mycotoxin levels somewhat. Cleaning should first be done with proper setting of your combine. A rotary cleaner is effective in removing remaining fines, provided flow rates are held below the rated capacity of the cleaner.

Several organic acids (proprionic, isobutyric, acetic, and mixtures of these with ammonium isobutyrate) are registered for use on high moisture grain in storage and sold under various trade names. Although these acids will not remove any aflatoxin previously formed in the grain, they will prevent growth of fungi if properly applied. Grain treated with an organic acid can be used only for livestock and poultry feed. The ensiling process that happens when corn silage is made will stop further aflatoxin production but does not destroy toxin formed prior to ensiling process. Spoiled or moldy corn silage should not be fed to livestock.

END USE AND FEEDING RECOMMENDATIONS

Corn known to contain more than 20 ppb may not be placed into the interstate commerce system, unless higher levels have been approved by the FDA. The processing of corn into nigh fructose syrups, sweeteners, ethanol, starch or etc. does not remove molds and aflatoxins. The processing tends to concentrate the toxins in the residue gluten feeds and end products. Processors routinely screen inbound corn for the presence of mold or off grade factors.

Blending lots with a high level of contamination with uncontaminated corn is not permissible if the corn is to enter interstate commerce. With careful sampling and analysis, most contaminated lots of corn can be used locally for feed. Very thorough mixing is necessary because blending does not diminish the aflatoxin concentration in affected kernels, it only dilutes the number of contaminated kernels per unit of weight. Both lots should be dry and clean in order to avoid the inevitable segregation by moisture and particle size.

General feeding recommendations of aflatoxin contaminated grain that apply to all species are difficult to make. Livestock producers

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END USE AND FEEDING RECOMMENDATIONS . . . continued

should avoid feeding grain containing more than 20 ppb to poultry, young swine and small calves. Levels up to 100 ppb can be fed to feeder cattle and beef cows. Feeds containing higher levels than this should be diluted to no more than 100 ppb on the farm. Aflatoxin contaminated grain should not be fed to lactation dairy cows or to any livestock that is severly stressed or exposed to infectious diseases.

Livestock producers should contact their veterinarian or feed nutritionist for help in determining feed rations.

FOR MORE INFORMATION

For more information, contact the Iowa Corn Growers Association, the Iowa Department of Agriculture and Land Stewardship, or your local ISU County Extension office.

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SPECIAL HARVEST ISSUE

## AFLATOXIN PLAN OF ACTION

The Iowa Corn Growers Association formed an industry task force to deal with aflatoxin in August of 1988. The task force included Iowa State University specialists in Veterinary Medicine, Plant Pathology, Grain Quality, Statistics, and Diagnostics, Iowa Dept of Agriculture and Land Stewardship, Iowa Farm Bureau, Iowa Grain and Feed Association, and Iowa Institute of Cooperation.

This task force implemented a monitoring program, gathered and disseminated appropriate information about aflatoxin, and advised regulatory agencies and the Iowa Legislature on what was happening with aflatoxin and how to handle the situation.

This task force has set an outline for the needs of the state of Iowa for 1989. In the event that weather conditions are such that a suspected incidence of aflatoxin may exist, then the appropriate organization will begin to monitor stressed areas for early detection of aflatoxin. In the event that excessive levels of aflatoxin is found, then responsibilities for action will be defined and action steps will be taken.

Information about the situation will be distributed by the appropriate organizations to reach as many people as possible and inform them of their options. The trade must then deal with the options and make recommendations to farmers and grain dealers to prevent aflatoxin from becomming a problem in the food chain.

This action plan will also include a list of needed research for causes, testing, monitoring, decontamination, use, and effects of aflatoxin. Research can improve the situation and possibly prevent a severe problem in the future.

## AFLATOXIN OUTLINE

1. Develop and Implement Action plan for 1989 and beyond

    a. Monitor the crop hit the stressed areas first as early as possible.

    b. Assign responsibility for action and at what point Extension, ISU, Dept, Associations, etc

2. Distribute information to reach as many people as possible

3. Assess marketing options and what the trade must do to deal with the problem.

4. Develop a list of research needs now and in the future.

Mr. GRANDY. Now, let me begin with this, Mr. Miller, because I am concerned about the outreach between the Department of Agriculture and State associations and commodity groups.

It looks to me, from what happened in Iowa, is that the lion's share was done locally between the Iowa Department of Agriculture and Land Stewardship, Farm Bureau, corn growers and State University of Iowa. What is your relationship or what kind of initiatives have you undertaken to educate farmers as to the nature of this problem and what can we expect from the Department of Agriculture or the Federal Grain Inspection Service in the future to continue an outreach, because I think, if I understand you correctly, this is a problem that we are going to have to keep an eye on for quite some time.

Mr. MILLER. I appreciate your question, Mr. Grandy. I think that the point that I would make here is that last summer, when the drought indicated there might be a problem with aflatoxin, FGIS initiated actions with the Department's Drought Task Force, with ASCS and the Federal Crop Insurance Corporation to make these agencies aware of the possibility of an aflatoxin outbreak.

I think it was through some of that early alerting that the Drought Task Force at the Department made some of the State health departments and others aware of their responsibility to start checking for aflatoxin early. I know that on August 3, for instance, ASCS issued its first letter requiring aflatoxin tests for all the corn going into the Government loan program.

Mr. GRANDY. Let me just ask you this. In Iowa, you have 95 percent of the people in the Government program. I don't know how many of them are in the Iowa Corn Growers. But what do you think of the idea of instituting, for want of a better term, an aflatoxin hotline, so if a guy has corn in his bins and he is not sure whether or not he has aflatoxin contamination, he can call up and find out about the black-light test. He can find out, perhaps, from his local elevator whether or not storage over a period of time in dry weather, followed by rains, is going to exacerbate that.

Don't we have to concern ourselves with a cumulative effect with aflatoxin? I mean, we go from one drought cycle into perhaps another dry cycle. Is the susceptibility for aflatoxin greater this year than it was last year because of last year's drought?

Mr. MILLER. I don't think I know the answer to your last question, but regarding the question about the hotline, I think that the Extension Service and other entities here in the Department of Agriculture, along with FGIS, would be more than happy to cooperate in those kinds of efforts.

Mr. GRANDY. Let me just say——

Mr. MILLER. Excuse me. We felt we had initiated some proactive measures last summer to make people aware of the possibility. We met with different corn grower organizations and with National Grain and Feed Association's Grades and Weights Committee and talked about the possibility of an aflatoxin problem. So we felt that we had been talking with groups.

In fact, Mr. Tanner, my assistant for technology, had gone out to Iowa to the meeting at Iowa State University last September, in which the subject was aflatoxin. We felt that we were cooperating and working——

Mr. GRANDY. I am not saying you are not cooperating. I am just saying that I think that we need to perhaps maintain that level of communication because when there is this much corn produced in this much dry weather, I want to make sure that the education is out there so that people, if they don't know, at least know who to call.

It is my understanding, and correct me if I am wrong because I really am not that familiar with the biology here, does aflatoxin tend to concentrate? Is it concentrated in gluten, and if so, does FGIS monitor corn gluten for aflatoxin contamination?

Mr. MILLER. FGIS does not monitor the corn gluten. The Food and Drug Administration would have responsibility for monitoring corn gluten.

Mr. GRANDY. But they do.

Mr. MILLER. Yes, they do.

Mr. GRANDY. They do monitor corn gluten.

Mr. Chairman, I ask unanimous consent to proceed for a minute.

Mr. GLICKMAN. The gentleman can have as much time as he wants.

Mr. GRANDY. Thank you.

Let me just ask you this. As I understand it, there are no fungicides at this point to prevent this mold growth. There is nothing preemptively a farmer can do. Is that correct?

Mr. MILLER. I think we would have to say that there may be some fungicides that might be available to contain the crop. I think that it comes down to an economic question and also the timeliness of application of fungicide. It is almost an impossible situation to try to curtail, but I don't want to give you a blanket answer and say that there is not a product available.

Mr. GRANDY. But are you saying that these products are not available to the average producer because of cost? Are they not retail products? Are they not registered?

Mr. MILLER. The availability is questionable.

Mr. GRANDY. There is nothing that you can apply to a corn crop to detoxify, to reduce or contain the mold growth, or is there? When I ask you these questions, I mean commercially available.

Mr. MILLER. There are some products that are being touted commercially, but they have not necessarily all been approved by the Food and Drug Administration.

Mr. GRANDY. That is my point. I fear that there might be some products that would jump onto the market, trying to appear to be the chemical answer to aflatoxin. I just want to hear it out of your mouth that you don't have anything that you are willing to say right now somebody can buy in a store that will prevent or stop aflatoxin.

Mr. MILLER. No, sir.

Mr. GRANDY. One more question, Mr. Miller.

If you exceed your 20 parts per billion or even the 200–300 parts per billion if you are finishing beef cattle that you have in your statement, and you disallow that shipment, can contaminated corn be used for alternative uses such as ethanol, plastics, uses of corn that are not consumed? Is it all right to use these contaminated grain shipments for these alternative uses?

Mr. MILLER. Absolutely. We would encourage that.

Mr. GRANDY. All right, and there is no problem, as far as this particular supply line is concerned, with any of that corn being commingled with corn that would be consumed? As far as you know, through the Federal Grain Inspection Service, if the grain is shipped out and sent to an ethanol plant, there is no way that this contaminated grain could be mixed with grain that might be fed to livestock?

Mr. MILLER. Again, if the grain was identified as being in violation of the FDA guidelines, the Food and Drug Administration would have the responsibility to determine the destination and use of that grain. The shipper would be required to alert the Food and Drug Administration to let them know specifically of the destination and final disposition of that grain.

The Food and Drug Administration would have control during that time. We would not. I presume that the Food and Drug Administration would keep those records and we could make it available if you would like to see it.

Mr. GLICKMAN. Would the gentleman yield on that?

Mr. GRANDY. I would be pleased to yield to the chairman.

Mr. GLICKMAN. I think you raise a good question, because this has been a concern of mine a little bit about a regulatory gap here, kind of a black hole. What happens to contaminated grain that is held to exceed the FDA limits?

Now, as Mr. Grandy has asked you, that grain can go into the ethanol market or can go into the biodegradable market or the nonedible market, but I guess the concern is, can that grain end up in the food supply in some capacity? There may be no way for you to stop it, the FGIS, but—because you are not a regulatory agency, but can that grain end up somehow in the food supply, grain that exceeds FDA's limits?

Mr. MILLER. I would have to say that it is a possibility. I would seriously doubt that anyone would do that but it is a possibility.

Mr. GRANDY. Mr. Chairman, I have no further questions and yield back.

Thank you, Mr. Miller.

Mr. MILLER. I would just follow up to say that if, in fact, someone did deliberately divert corn that has been found in violation of the FDA guidelines into food use after it has been found to be in excess of the FDA guidelines, they would be in violation of the Food, Drug and Cosmetic Act and other Federal and State laws and would be subject to severe penalties.

I don't think that there are too many people who are willing to risk that once they have a known problem. They do have an alternative for it. It is not as if the only alternative is just to take it out and bury it.

Mr. GLICKMAN. Thank you.

Mr. Penny.

Mr. PENNY. Thank you, Mr. Chairman.

Mr. Miller, many nations, in buying grain from us, require that we test for the presence of aflatoxin. Do we routinely inspect all the grain coming in? And when I say "routinely," I mean every shipment that comes in is tested for the presence?

Mr. MILLER. We would not test in-bound shipments. Not routinely.

Mr. PENNY. Do-you leave that, then, to the individual buyer to test if they are concerned about the presence in the contract that they might have?

Mr. MILLER. That is correct. They may in turn ask us to test the in-bound grain, but that is not a mandatory requirement.

Mr. PENNY. Given the fact that we test outgoing grain—I understand you are called on to do the test whenever there is a foreign buyer that requires this as part of the contract. FGIS conducts the test?

Mr. MILLER. That is usually the case, but not always. A foreign buyer could specify in the contract to have some other entity other than the Federal Government provide the aflatoxin testing.

Mr. PENNY. Has there been a concern expressed about the need to have additional testing of incoming grain in this regard? Would it, given the fact that we are subjected to that kind of requirement in terms of outgoing grain, would it make sense for us to apply the same uniform standard for incoming grain?

Mr. MILLER. Mr. Penny, many of the companies, for their own information, do screen the grain as it arrives at the export. They would test it, using their own personnel, or they would contract out with possibly FGIS or a private laboratory to test it.

Mr. PENNY. I can understand that the companies, by and large, would be concerned about that, and as a matter of private business transaction, would want to have it tested, but in looking at it from the standpoint of American consumers, who are protected in the domestic market, or at least should be protected in the domestic market by the involvement of the FDA in monitoring the quality of the grain, shouldn't we have more than just the private firms involved in being concerned about the quality of the incoming grain?

Mr. MILLER. Again, I think the important point to remember is that most consumers don't eat raw corn. Most of us eat cornmeal or corn grits or other processed corn products. They are inspected by the Food and Drug Administration. I think that is the reason why——

Mr. PENNY. At the point of processing———

Mr. MILLER. They have focused their attention on the processed commodities, rather than the raw material.

Mr. PENNY. What about grain quality generally and grain standards? It is my understanding that grain that is cracked or broken, grain that has foreign material, is more susceptible to an incidence of aflatoxin.

What, if anything, could we do in the area of grain quality that might mitigate against the presence of this?

Mr. MILLER. Although I have not seen any data to support this, I have been told that the aflatoxin content is higher in the foreign material portion of the corn. We would expect that if there was less foreign material, there would probably be less of a carrier or host for the aflatoxin.

Mr. PENNY. Does your office have any legislative recommendations in that regard? Are you considering any modifications in grain standards along those lines?

Mr. MILLER. Yes, we are. We are currently in the process of conducting a study in conjunction with the National Corn Growers Association and many of the processor and merchandising industry

associations to look at the feasibility of establishing new factor limits for broken corn and foreign material. We are about to embark on an economic-impac study to establish the basis for whatever those new levels might be.

We would expect that that study will be completed in approximately a year and a half.

Mr. PENNY. In time for the next farm bill?

Mr. MILLER. I beg your pardon?

Mr. PENNY. In time for the next farm bill?

Mr. MILLER. I doubt if it will be done in time for the next farm bill. I am not sure that the next farm bill would really be necessary to accommodate this change. We can make this change administratively.

Mr. PENNY. No, no, I know that it wouldn't.

Thank you, Mr. Chairman.

Mr. GLICKMAN. Thank you.

Mr. Sarpalius.

Mr. SARPALIUS. Mr. Miller, do you have any idea of what percent of the total amount of grain was damaged by this?

Mr. MILLER. No, sir, we do not.

Mr. SARPALIUS. You don't have any guesses?

Mr. MILLER. No, sir.

Mr. SARPALIUS. Do you have any idea—do you know of any universities or anybody that is doing research to try to find a means of treating, chemicals that might be available or anything like that?

Mr. MILLER. I don't know of any off the top of my head, but I would be very surprised if some of the major land-grant universities in the Corn Belt were not looking at it. I can't cite the individual researchers for you this morning, but I am sure there are researchers out there at places like the University of Illinois and Iowa State University and others in the Midwest that are looking at it.

Aflatoxin has been a problem in the Southeast for a long, long time because of the extreme heat conditions and I would be surprised if there aren't some researchers at the University of Georgia or others that aren't looking at it also.

Mr. SARPALIUS. In your opinion, what do you think Congress should do to try to help deal with this problem?

Mr. MILLER. I think that the best thing that Congress could do to help us is to help us avert management by media hysteria. Quite frankly, we think that the Food and Drug Administration and the other government agencies that are involved in protecting the human food supply are doing a good job. They are in front of the problem and, quite frankly, the media hysteria certainly doesn't help our export situation any. We quite frankly are very concerned that the destruction of foreign markets that takes place every time we have articles appear in major national newspapers takes years and years and years to recover those markets that are lost because of somebody's opinion that was not necessarily based on the facts.

We have concern about that. If Congress can help us in dispelling some of the hysteria that surrounds these types of food safety issues, we think that would be very positive.

Mr. SARPALIUS. So you think it would be wise for members of Congress to express that maybe this problem isn't as severe as what it may look like it is?

Mr. MILLER. I certainly think that is the case.

Mr. SARPALIUS. Thank you.

Mr. VOLKMER. Will the gentleman from Texas yield?

Mr. SARPALIUS. Sure.

Mr. VOLKMER. In that regard, after reviewing this, is the aflatoxin that we are seeing from the 1988 crop widespread throughout the Corn Belt?

Mr. MILLER. No, it was not. It was fairly well isolated in a few of the States. Again, almost all of the States in the Corn Belt established extensive sampling programs. I am aware of almost all the States in the Corn Belt that had testing programs to screen the crops and the problem was very isolated in a few local areas.

Mr. VOLKMER. My review of this testimony so far that I find we are going to have here later on leads me to believe that we may have the eastern part of Iowa and parts of Illinois and that is about it, where it is over 20 parts per billion.

Mr. MILLER. Those were the most severely affected areas, Mr. Volkmer.

Mr. VOLKMER. Right. I mean, you look at other major corn-producing areas, such as Indiana and Ohio, other parts of Illinois, western parts of Iowa, Nebraska, Minnesota, you don't find this aflatoxin problem. Is that correct?

Mr. MILLER. That is correct, Mr. Volkmer.

Mr. VOLKMER. So when we look at the total amount of corn produced and corn exported, it isn't that large an amount and it appears to me, from what you have said, that we pretty well have our hand on where it is and where it has occurred.

Mr. MILLER. We think that is the case. We think that the Food and Drug Administration has a good feel for where the problem is also.

Mr. VOLKMER. Thank you very much.

I thank the gentleman from Texas.

Mr. GLICKMAN. Mr. Jontz.

Mr. JONTZ. Thank you very much, Mr. Chairman.

Mr. Miller, if I understand your testimony correctly, so far in 1989, about 75 percent of exported corn has been tested for aflatoxin. The decisions about what corn would be tested have been based on the requirements of the customer, is that right?

Mr. MILLER. That is partially correct. The 75-percent figure reflects that percentage of the contracts where it was a contractual requirement. I had indicated earlier in my statement that we have initiated a complete monitoring of all of the shipments to the Soviet Union, Japan and Mexico, again because of the significance of those markets. We have voluntarily established a monitoring program that was in addition to the contractual requirements.

So, actually, the 75-percent figure understates the amount of the export crop that we have looked at.

Mr. JONTZ. Is there some reason our country doesn't simply adopt a policy of testing all corn for export markets? It would seem to me that media hysteria generated by a problem with a small

market would be just as damaging as a problem coming from a major market.

Why don't we just prevent that sort of problem by having a blanket policy that we don't let corn leave this country without being tested?

Mr. MILLER. That is a good question. I think it comes down to cost. Who is going to pay for the cost of the mandatory testing for providing this guarantee to our customers?

Mr. JONTZ. Who is paying for it now?

Mr. MILLER. Usually the shippers will pay for the cost. I should point this out for the record, Mr. Jontz, that the Federal Grain Inspection Service has lost more than a quarter of a million dollars this year on the aflatoxin testing program that we have undertaken that we were not able to recover costs for.

Mr. JONTZ. That is a concern, but if we are now testing 75 percent of the grain that is being exported, and if your concern is to protect our export markets and to avoid problems which could come from adverse media coverage, I would think that it would be a much sounder policy to be safe rather than sorry and test all the exports. It would cost a little more, obviously, but I would think that the security that that would bring about from the standpoint of an understanding that it was our policy that all export grain was tested would be worth the cost of protecting our markets.

Whose decision really is that? Who has the authority within USDA to say that would be our country's policy?

Mr. MILLER. I believe that I could make that decision if I——

Mr. JONTZ. Good.

Mr. MILLER. Mr. Jontz, the decision to start testing all the shipments to the Soviet Union, Mexico and Japan was done at my request, but I would point out that as a result of that monitoring, we have not seen evidence of a problem that would warrant a 100 percent monitoring level.

If we felt there was the need for that, we would have already opted to do so, but our experience has not indicated that there is a problem that would warrant the additional cost of moving to 100 percent monitoring.

I admit to you that it would have a very good public relations ring about it, to say that we are monitoring 100 percent. In our view, monitoring 75 percent indicates that we are doing a good job of protecting the export markets. Therefore, we have decided—because we have been losing money on it—not to go ahead and spend the extra money to do that last 25 percent.

Mr. JONTZ. I guess you have to weigh the potential costs which could occur were an incident to arise as a result of failure to test and the problems this could cause for our export markets against the cost of doing the testing. I find it troubling—puzzling, I guess, that you have adopted a policy that corn going to some markets is going to be tested and corn going to other markets is not going to be.

Even though you have the bigger markets tested, I would think that the adverse publicity and the concern by customers would be equally as great from an incidence with a smaller market than it would be with a larger. I am not sure that I understand the distinction between the two, but I would ask you to give some thought to

the relative merits of extending the testing program so that you could come before the Congress or make a statement to the media that any customer of foreign export from our country could be assured that testing had been done, regardless of the size of the customer, regardless of where the corn was heading, it would be tested for aflatoxin.

I see that my time has expired, Mr. Chairman, thank you very much.

Thank you, Mr. Miller, for your helpful statement.

Mr. GLICKMAN. Thank you, Mr. Jontz.

Before you leave, I just have a couple of final comments. One is that I would hope that we would protect U.S. citizens as much as we would protect foreign customers. It is nice to protect our buyers overseas, but I hope that we have the same attitude with respect to citizens of this country.

Mr. Grandy asked you a question, which you said you didn't know, and I wanted to confirm this. Is there a problem when you have droughts, repetitive droughts year after year? Does that make the aflatoxin problem worse or not? Do you have knowledge of that effect?

In parts of the corn country, if we were to be in a drought again this year, would that have some sort of a material enhanced affect on aflatoxin or do we know?

Mr. MILLER. I am advised by staff that we really have no historic basis to determine that, Mr. Glickman.

Mr. GLICKMAN. The second question has to do with something else that Mr. Grandy and I were just talking about, the nature of a fungus. Twenty parts per billion or whatever the number of parts per billion that you have, there is still a fungus in that grain and fungus grows, spores move, and how do you control the growth of the fungus once it is in the grain?

I mean, you test for 20 parts per billion, but can that become 300 parts per billion in a month and 6000 parts per billion? Does it grow, let's say—aflatoxin has been called a carcinogenic substance. Does it grow like a cancer grows in terms of enhanced contamination?

Mr. MILLER. Mr. Glickman, there is no question but what the aflatoxin can grow during storage if, in fact, the grain is not stored properly. We advocate—and the recent Office of Technology Assessment study indicates that grain quality is very dependent upon proper storage practices to keep the moisture levels down and also to keep the grain as clean as possible when it goes into storage. The addition of mold inhibitors—all these things can help improve the quality of the grain. There is no question about it.

It is a very complex question and requires many solutions to the problem.

Mr. GLICKMAN. We probably should have had the FDA here at this hearing because we are asking you some questions that you are not involved with; but you did talk a little bit about this media hysteria. I wanted to just relate to you two items that were in a Wall Street Journal yesterday because I think you ought to have the opportunity to comment on them.

One is:

According the USDA, about 1 percent of the overseas-bound corn tested by grain inspectors in the past month contained more than 20 parts per billion of aflatoxin.

Is that a correct statement?

Mr. MILLER. I will say yes. I think that the important words in that sentence are the "overseas-bound shipments." That was material that was presented in a shipping bin elevator for testing, for export. During the testing, it was discovered that sublot contained over 20 parts per billion and that material, then, was——

Mr. GLICKMAN. Was removed.

Mr. MILLER. Was removed and not exported from the country.

Mr. GLICKMAN. What happened to it after it was removed?

Mr. MILLER. It was returned back to the house.

Mr. GLICKMAN. And then what happened?

Mr. MILLER. I presume it was probably blended with other grain of lower levels and presented at some point for inspection or diverted to another usage for which it could still be safely utilized.

Mr. GLICKMAN. Yes.

Mr. Jontz.

Mr. JONTZ. If the gentleman would yield, this gets to my question of why aren't we testing 100 percent of the exports here. You would not have found these problems had you not been testing 75 percent of the exports and the point you made to me is, well, we took that grain off the market. That is great, so why aren't we testing the other 25 percent of the exports so we can take that grain off the market if there is a problem there?

If you don't test, how do you know that there isn't a problem? It would make sense to me that if 1 percent of the grain that was tested demonstrated a problem, then it is likely that 1 percent of the grain that wasn't tested would demonstrate a problem and perhaps I misunderstand the situation, but if I hear clearly what you answer was to the chairman's question, I would think that is pretty conclusive evidence as to why a universal testing policy makes sense.

Do you have some response to that point?

Mr. MILLER. Not really, other than to say that the vast majority of the grain that has been officially tested, obviously, passed all of the FDA guidelines for safe usage.

Mr. JONTZ. One percent didn't. Is that correct?

Mr. MILLER. That is correct.

Mr. JONTZ. And if that 1 percent had been bound—excuse me, if grain that was not tested is bound for an export market and a problem arises as a result of 1 percent of the untested grain and media coverage of that occurs, is that not likely to have an adverse impact on our export markets?

Mr. MILLER. It very well could have, Mr. Jontz.

Mr. JONTZ. Thank you.

Mr. GLICKMAN. I guess my concern, Mr. Miller, is that I think our export customers ought to be real happy because we are giving them really preferential treatment over domestic customers. You know, you indicated that if that grain were, in fact, contaminated, it would then go back to the elevator and could be blended or mixed with other grain for domestic purposes.

I think that is what you said, it could happen, or for export, theoretically, if it were below the 20 parts per billion. I would ask you

this question, do you think that mixing of clean grain with aflatoxin-contaminated grain should be prohibited?

Mr. MILLER. That is a tough question, Mr. Glickman, because, as you know, 100 percent of the U.S. crop gets marketed in some form or fashion. Either farmers feed it and it is marketed through livestock or it is moved to the marketplace and sold as cash grain.

We have to think about who is impacted by a policy of that type. There would be a lot of farmers who would be adversely impacted if, in fact, we didn't allow the blending of the grains. The blending does allow for the utilization of corn that otherwise may not be used.

Mr. GLICKMAN. I guess my concern about the blending goes back to the nature of this fungus. If it is a growing fungus, then blending contaminated grain with clean grain contaminates all the grain, theoretically. Now, I am not a scientist, so I don't know if that happens. I don't know if there are spores that move and attach themselves to other pieces of corn and then it grows some more. That is why we are looking at you, as the expert, to tell us how this thing grows and whether, by blending, we could be increasing the damage to the clean grain, so to speak.

Mr. MILLER. Mr. Chairman, there is no question that if we blended it and it went back into long-term storage and it was high in moisture levels, under those conditions, you could have continued fungal growth. There is no question about that. That is not likely to happen under these conditions.

We are talking about blending at export locations that are going to be in relatively short transit, unloaded, and used immediately for livestock feed. In many cases, the original levels, even if they were over 20 parts per billion, I am not aware of any that were over 50 parts per billion at export when the grain was presented for inspection.

That means that that corn could have been used for almost all types of livestock feeding, with the very few exceptions of immature animals including poultry and lactating dairy cows. It could have been used for almost any other type of livestock feed.

Mr. GLICKMAN. OK, now let me just finish and I will yield.

I think, again, for the export business, we are doing a better job. I want to—so that all the customers of ours in the world know—that if you are outside the United States, you are getting a pretty good deal because this thing is really getting inspected.

I want to give you one more comment from this Wall Street Journal article of yesterday.

> Since the fall, Federal inspectors have found dangerous levels of aflatoxin in 7 percent of sampled unprocessed corn slated for use in human food.

I presume that is domestic. I wonder if you could comment on that statement, if you think that is accurate or not.

Mr. MILLER. I would be glad to comment. I think that statement clearly indicates, as well as anything I can present this morning, that the FDA's domestic inspection system is working. The Food and Drug Administration has a network in place to try to detect and identify hazardous lots of deleterious substances throughout our food chain and the fact that they have reported results indicates that the detection system is working.

There is no question but they could increase their monitoring. They could do additional testing, but the fact is there is a system in place; it seems to be working very well; and you have to take that in conjunction with the network for testing undertaken by private companies.

I think the American public has the most wholesome food supply of any country in the world and I don't think there is anybody who can dispute that fact.

Mr. GLICKMAN. I think both Mr. Jontz and Mr. Volkmer want to follow up on that, so, Mr. Volkmer, did you want to follow up?

Mr. VOLKMER. The only thing I would like to comment on on the question of blending is that as I see what happens to our grains, especially those going to export, we are blending corn right along the process. When it comes in from the field and it goes to an elevator along the river, it isn't kept separate in that elevator.

Then when it comes out of the elevator and goes in that barge and goes down the Mississippi, it isn't kept separate in that barge and then when it goes from the barge into the export elevator at Galveston or wherever along the Gulf, it isn't kept separate.

Is that correct?

Mr. MILLER. That is correct.

Mr. VOLKMER. So we are blending corn all the time and wheat and everything else.

Mr. GLICKMAN. I guess my point is that if we had a contaminated sample of grain at the elevator that was found to be contaminated, then it could go back and be blended either for further export or else for use in the domestic market, that is my understanding.

Mr. Jontz, did you have a follow-up?

Mr. JONTZ. If I might, Mr. Chairman, if the statement from the Wall Street Journal is that 7 percent of the tests which were made indicated a problem with aflatoxin, that the standards were exceeded, what I would like to know, and perhaps you have covered this and I missed it in your statement, is what percent of the product is being tested? I think that is the key question. Do we have corn that is entering the food processing—being used by food processors, et cetera, or being fed, which is not being tested?

Obviously, we have a lot of corn used on the farm that isn't being tested, but I am not sure I know where else corn is going where it isn't tested. The fact that we have 7 percent of the corn over the standards indicates to me that we better be asking how thorough the testing program is.

You have a lot of confidence, Mr. Miller, in that testing program, but I think what is not clear to us in the Congress, and perhaps was not clear to the media, is the extent to which the net of testing is so comprehensive that we can be assured that aflatoxin is detected no matter where the corn goes where it could be consumed domestically.

Can you respond to that question?

Mr. MILLER. I would be glad to respond to that question. I think it is a fair question. I think the American public deserves an answer to it.

I have before me a Talk Paper that was issued by the Food and Drug Administration on February 27, 1989, and I would like to insert it into the record, Mr. Chairman.

Mr. GLICKMAN. A Talk Paper on this issue?
Mr. MILLER. It is a paper on this issue.
Mr. GLICKMAN. Without objection, it will be in the record.
[The Talk Paper follows:]

F D A
TALK PAPER
FOOD AND DRUG ADMINISTRATION
U.S. Department of Health and Human Services
Public Health Service 5600 Fishers Lane Rockville, Maryland 2085

FDA Talk Papers are prepared by the Press Office to guide FDA personnel in responding with consistency and accuracy to questions from the public on subjects of current interest. Talk Papers are subject to change as more information becomes available. Talk Papers are not intended for general distribution outside FDA, but all information in them is public, and full texts are releasable upon request.

T89-13
Feb. 27, 1989

Bill Grigg
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DROUGHT INCREASES AFLATOXIN PROBLEM FOR FARMERS, PROCESSORS

An account in the Wall St. Journal Feb. 23 accurately portrayed an increase in aflatoxin, a natural carcinogen produced by a mold, in the 1988 corn crop, primarily in the Midwest as the result of drought. The problem has required the diversion of some corn to feed non-dairy cattle, so that human exposure is minimized. (See Talk Paper T88-73 of Oct. 4, 1988.)

Unfortunately, the article, in dwelling on the problem in crops, left some readers greatly concerned about consuming milk and corn products. FDA does not believe such concern is warranted because there is plenty of aflatoxin-free corn available for human consumption, and several layers of protection are in place. Here is the situation:

MILK -- FDA has an action level of .5 parts per billion for milk in order to keep aflatoxin exposure to a minimum. On Oct. 3, 1988, FDA reaffirmed the action level to all state health officials. The states and the state-supported National Conference on Interstate Milk Shipments, which has the prime responsibility for monitoring milk, expanded monitoring. Some milk in Texas, Minnesota, Iowa and southern Illinois has tested higher than .5 ppb and has been dumped. To be sure their milk will not be lost through

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dumping, farmers are asking for assurances that the corn they buy for dairy cattle is within safe limits.

SWEET CORN -- The corn hit by the increase in aflatoxin is what is generally called field corn, not sweet corn or "eating ears." To confirm that sweet corn was not a problem, samples of sweet corn -- canned, canned creamed and frozen -- were recently tested. They showed no aflatoxin.

FIELD CORN -- FDA's tests of grain since Oct. 1 have shown about 6 percent, or 95 samples out of about 1,650, to be above the 20 ppb action level from field corn. FDA's testing is concentrated in areas with known or potential problems. FDA's policy is to bar the higher aflatoxin corn from human use and/or divert it to safe use as animal feed. Besides FDA, USDA and the states, manufacturers and millers who purchase corn for breakfast cornflakes, corn flour and grits test for themselves (or have tests done) to ensure they have the safe raw material they're paying for. (Otherwise, they risk having to destroy their products, at a loss.) Industry data from all over the country show less than 2 percent of 6,000 samples to be above 10 ppb.

As a result of this testing, and the removal of tainted grain, FDA's tests of finished products -- cooked cereal, dry cereal, tortillas, corn chips and popcorn -- have been either totally negative or under 20 ppb..

-MORE-

CORN FLOUR and MEAL -- About 2 percent (6 of 261 samples) has been found above 20 ppb, in FDA's tests. FDA policy is to remove the violative product from the market. Incidentally, aflatoxin would be significantly reduced by subsequent cooking of the grits or corn flour or meal.

USES FOR HIGHER AFLATOXIN CORN -- In previous years, on a case by case basis, FDA has permitted corn with higher aflatoxin levels to be used for non-dairy animals. This was based on scientific data indicating that aflatoxin levels higher than those for humans were not harmful to the animals and did not result in aflatoxin in the meat or eggs. In the fall of 1988, when FDA rewrote the guidelines for aflatoxin in feed corn, it used the same rationale as it had in the previous years' case-by-case exceptions in setting levels permitted for feed for non-dairy animals.

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Mr. MILLER. I would just like to cite from the field corn section in it. It talks about:

> FDA's tests of grain since October 1 have shown about a 6 percent or 95 samples out of about 1650 to be above the 20 parts per billion action level from field corn. FDA's testing is concentrated in areas with known or potential problems. FDA's policy is to bar the higher aflatoxin corn from human use/or divert it to safe use as animal feed.
>
> Besides FDA, USDA and the States, manufacturers and millers who purchase corn for breakfast cornflakes, corn flour and grits test for themselves or have tests done to ensure that they have the safe raw material they are paying for. Otherwise, they risk having to destroy their products, at a loss. Industry data from all over the country show that less than 2 percent of 6000 samples to be above 10 parts per billion.
>
> As a result of this testing and the removal of tainted grain, FDA's tests of finished products, cooked cereal, dry cereal, tortillas, corn chips and popcorn have been either totally negative or under 20 parts per billion.

There are other parts here relative to the corn flour and meal and also the diversions for other higher aflatoxin-containing corn that would be in this document that would be a part of the record, Mr. Chairman.

Mr. GRANDY. Mr. Chairman.

Mr. GLICKMAN. Yes, Mr. Grandy.

Mr. GRANDY. Thank you.

Mr. Miller, I just want to read a couple of excerpts from this Green Sheet, Iowa Corn Growers report, and then comment a little bit about what Mr. Jontz and Mr. Glickman were talking about.

They say, when they are discussing in this sheet where molds and aflatoxin come from:

> If grain is not properly stored, the tiny mold spores can increase rapidly, leading to higher aflatoxin levels and significant problems in the end use of the corn.

They go on to talk about to determine if you have aflatoxin, and this is where your black light test comes in, and it reiterates everything that you said, but this concerns me. When they talk about what a 20-part-per-billion sample means, that is roughly equivalent to 20 kernels in a rail car, 3,500 bushels. Because aflatoxin is not evenly distributed in all kernels, the collection of a large sample—this would be preferably 10 pounds, but certainly no smaller than 5 pounds—is essential.

Now, going back to what Mr. Jontz was talking about, I won't argue figures with you and how safe the supply is because I do not, in any way, mean to suggest that we are putting populations at risk, but it seems to me that this particular methodology is at some point going to be called into question. I am not sure that this particular test is going to instill confidence in the consumer, whether he is domestic or foreign.

Going back to what the chairman talked about, if these spores are increasing or can increase rapidly, what guarantee do we have that this grain is stored properly? How much does the farmer know and how much is he unwittingly perhaps allowing contaminated grain to come into the supply line, and if he is, where do you jump in and make sure that it does not move down the supply line and into the marketplace?

Mr. MILLER. I will say that it is difficult for us, when we are not put into the position of inspecting the grain when it is coming off the farm, to be the policemen for the grain supplies as it sits out in

the country in farmers' storage. It is an almost impossible situation.

I think that the steps that the ASCS took in requiring the corn that was put into the Government loan program to be tested for aflatoxin is the first step in raising the farmers' awareness level to their responsibilities in maintaining inventories in optimum storage conditions.

There are those who would advocate even additional measures be taken in requiring mandatory inspections coming from the country. I personally don't favor that. I think that the marketplace provides for a system of inspections as the grain moves through the market channels that accommodates the needs of the buyer and seller. We have an overall national network of inspections that protects the human food supply.

Again, to what extent do we have to go to deal with an isolated problem.

Mr. GRANDY. I won't dispute anything you have said. I think, though, that at some point, it would be worth the Department's time and energy to perhaps poll corn growers around this country, whether they are in eastern Iowa or western Illinois or wherever, and try to get a consensus as to if there is going to be a cost to the producer for increased quality, for enhanced quality, whether we are talking about foreign material or aflatoxin, whether or not they are not willing at this point to accept some of that cost.

I agree with you, if we do instill tighter inspections, somebody is going to pay for it, probably the producer first and the taxpayer second. But as we visit these kinds of issues, and they are so heavily volatile in terms of the public's attention, I think that we might be at a point where it would be worthwhile to assess how much the consumer, whether he is growing corn or eating it, is willing to pay for enhanced inspection, whether it comes from you or FDA.

Mr. Miller, thank you.

Mr. GLICKMAN. Mr. Miller—let's see—Mr. Jontz, I know one of the witnesses has to move on, so——

Mr. JONTZ. I just have one final question.

Mr. GLICKMAN. Sure.

Mr. JONTZ. Since only 1 percent of the grain headed for export markets is determined to be above the dangerous level, and since it is a small percentage of the grain that is tested for domestic markets, why don't we just segregate that grain and require that it be used for some industrial use like ethanol production, rather than taking the risk that it is blended back and could show up somewhere else?

Why don't we just take that simple step and provide assurance to the public and to our export customers that that grain will not show up somewhere else again where it could cause a problem?

Mr. MILLER. Two points. First of all, I think that I would caution you regarding using the 1-percent figure as an extrapolation for the entire U.S. corn crop. This data was generally based on analysis of sublot samples during a 1-month time period. Again, I don't know that that is representative of the entire U.S. crop or not, but I will caution you, when using that as the figure for the extrapolation for the national crop that might be outside the 20 parts per billion.

Second, the real problem we are trying to isolate is that corn at export is really out of position for diversion back to an alcohol fuels use or for biodegradable plastic or something like that. The corn, once it is in an export location on the Mississippi River or Texas Gulf or Pacific Northwest, is out of position. There are a lot of additional freight and handling costs associated with getting it back into the interior close to the alcohol plants and the plastic——

Mr. JONTZ. So what is happening to it now?

Mr. MILLER. It is being blended off.

Mr. JONTZ. It is being blended off?

Mr. MILLER. Yes.

Mr. GLICKMAN. I would just, first of all, thank you for coming and I know that you cannot answer all the questions, but I would urge you not to—I believe the marketplace ought to work, but I have always felt when it comes to some of these health and safety issues that you can't always rely on the marketplace to do the inspection process. I mean, that is why we inspect meat at meatpacking plants and that is why we have FAA inspectors inspect engines on airplanes because we have learned that you just can't always let the fox watch the chicken coop in this world.

I would hope that you would listen to some of the testimony that is coming later on because if we could develop testing equipment that would allow producers to do this in a quite feasible, easy fashion, it may be more likely that we would do a better job of ensuring that there is no grain that is over the 20 parts per billion that gets into the export market.

But anyway, we appreciate very much that you have been here today.

Mr. MILLER. Thank you.

Mr. GLICKMAN. Thank you.

Next, we have a panel of witnesses. Dr. Steve Tannenbaum; Dr. David Livingston; Mr. Leonard Stoloff; and Mr. Rod Leonard.

I will start out by saying before you begin to testify, there have been a couple of folks who have indicated that they have testing equipment, either similar or competitive, and that some of you will be testifying in reference to a testing procedure. One, this committee does not put its stamp of approval on anything. This is not a Good Housekeeping operation.

Two, if others wish to bring forward to us their equipment, we will be more than happy to put that in the record as well. I think that some of you had come to us and told us that, as an example of what can be done, you have some potential equipment here. So that is the reason that—I know that, Dr. Livingston, you have been in my office and we have talked about this before.

But it is not to, in any event, be exclusive of other equipment that is out there that may be just as good, may be better, so I just want to make that clear for the record.

Again, any of those people who wish to have their statements in the record, we will be glad to take those and the record will be open for 10 days.

Doctor, I think the way we have it listed here is Dr. Tannenbaum, Dr. Livingston, Mr. Stoloff and Mr. Leonard. Why don't we go ahead and take you in that order and your statements will

appear in the record in their entirety, so if you wish to summarize, that is fine.

I know that there is a piece of machinery up here for us to look at as well, which I think we would probably like to get some idea on how it works.

Why don't you proceed.

## STATEMENT OF STEVEN R. TANNENBAUM, PROFESSOR OF CHEMISTRY AND TOXICOLOGY, MASSACHUSETTS INSTITUTE OF TECHNOLOGY

Mr. TANNENBAUM. Thank you very much, Mr. Chairman. Thank you for giving us the opportunity to be here today and to testify at these proceedings.

My name is Steven Tannenbaum and I am a professor at the Massachusetts Institute of Technology. My field is chemistry and toxicology and I also have a background in food science.

With me, as you noted, is Dr. Livingston, who is a professor at Harvard, and also Dr. Tom Hansen, who is from VICAM Incorporated.

I have a very brief statement which I would like to read. I don't think it will take very long and I will be very happy to answer any questions.

The statement actually is structured along the lines of trying to answer a series of questions. The first question is whether aflatoxin contamination of food crops results only from extraordinary weather conditions, such as existed in the Midwest last summer, so that it would be likely to occur infrequently?

Now, it is difficult, if not impossible, to predict when or at what levels aflatoxins are likely to be found in different food crops. The FDA lists the following as crops susceptible to aflatoxin contamination: corn, peanuts, sorghum, rice, wheat, soybeans, walnuts, almonds, pecans, pistachio nuts, Brazil nuts, figs and the edible tissue from food-producing animals, including meat, eggs and milk of the animals that consume these compounds. This is part of the problem.

This is not to say that aflatoxins are always present in these commodities, only that contamination can occur when storage or other conditions permit growth of the toxin-producing fungus, which is ubiquitously distributed. Available evidence and facts suggest that both the frequency of contamination and levels of aflatoxin present in different crops show wide geographical and seasonable variations.

As a result, the problem tends to be regarded as regional and sporadic in nature. In fact, in prior years, emphasis was placed on corn products in the southeastern United States, while this year, the problem was more acute in the corn crop in the Midwest.

The basic lesson is that the problem can occur anywhere at any time and the only assurance of safety available to us, until we can control the weather, is wider and more frequent surveillance.

Extensive data relevant to this issue are available for peanuts, but less information exists for other crops. Lack of information is due mainly to extensive surveillance for aflatoxin contamination of the other commodities, compared to peanuts and peanut products.

Because aflatoxins were originally discovered in peanuts nearly 30 years ago, manufacturers of foods and feeds containing peanuts came under intense scrutiny immediately thereafter.

In the intervening period, development and application of an effective inspection, storage, sorting and testing procedures have enabled the development of an effective quality assurance component of good manufacturing practice that has made it possible to maintain aflatoxin contamination at levels substantially below action levels set by FDA.

In principle, many of these same procedures can be adapted for use with other food crops and their implementation could similarly protect the food supply from excessive aflatoxin contaminations.

Now, I would like to skip on to the question of how serious a public health problem is aflatoxin contamination of foods. Concern about aflatoxin contamination is based upon their ability to cause cancer, as indicated by a very impressive amount of information about their effects in both experimental animals and people exposed to them.

Cancer has been experimentally induced in many animal species, including fish, bird, rats, mice, ferrets, tree shrews and monkeys by long-term feeding of diets containing aflatoxins at different levels. In the most sensitive species, tumors are caused by dietary levels of 10 parts per billion or less. Liver cancer is the main form of the disease induced by aflatoxins, but other cancers are also elevated in some experiments.

A second line of evidence of carcinogenic risk from aflatoxins comes from extensive epidemiologic studies of liver cancer incidents in human populations consuming diets contaminated with aflatoxins at different levels. Taken together, results of these studies, conducted mainly in Africa and Asia, show a strong correlation between elevated liver cancer incidence and amount of aflatoxin eaten.

The data from various parts of the world, including the United States, where aflatoxin intake and liver cancer incidents are relatively low, fit well together. Analysis of the combined human and animal data led the International Agency for Research on Cancer, which I might say is a very highly respected organization and quite conservative in its judgments, to conclude that the combined evidence was sufficient to designate aflatoxins as human carcinogens. These are the only food-borne chemicals so to be designated by this agency.

This IARC document, which resulted from the deliberations of many distinguished scientists, and I might add, took into consideration the comments and papers of Dr. Stoloff, who is a member of this panel, deserves your attention and I am providing a copy for the use of the committee, of the subcommittee and its staff.

Now, what are the ramifications of not increasing surveillance, and I think this has been a discussion which has taken place this morning in part. One of the problems that has not been brought up is that aflatoxins are extremely toxic to poultry and fish. They are somewhat toxic to pigs and they cannot be fed to lactating animals because it gets into the milk supply.

Other countries, notably Europe and Japan, have lowered their standard to 5 parts per billion or less. If we cannot export contami-

nated grain and if it cannot be fed to domestic animals, higher levels of contamination will enter the United States food supply, to the detriment of our health and that of our children.

On the other hand, increased testing of corn, in particular, will allow segregation of contaminated lots, produce higher quality material for export and lead to lower levels of contamination in the domestic food supply.

Let us look at the peanut industry as a positive example of what agri-industry can accomplish through effective quality control.

That is my statement, Mr. Chairman.

[The prepared statement of Mr. Tannenbaum appears at the conclusion of the hearing.]

**STATEMENT OF DAVID LIVINGSTON, M.D., HARVARD MEDICAL SCHOOL AND CONSULTANT OF VICAM, INC., ACCOMPANIED BY THOMSEN J. HANSEN, DIRECTOR OF CHEMISTRY, VICAM, INC.**

Dr. LIVINGSTON. Thank you, Mr. Chairman. I also appreciate the privilege of being able to come and speak before you today.

My message is very simple. With regard to questions that have been asked here and statements made by Mr. Miller concerning the availability of new technology that would allow simple testing of aflatoxin, the news is excellent. American technology has made it possible, using a variety of approaches, to measure aflatoxin in a tractable way.

One such method is going to be presented to you this morning, if you like. It can be done on a bench top in a room such as this, in a dusty elevator, in a field mill, in a laboratory or in a moving automobile, if necessary, if there were electricity.

The point I want to make is this method, which, in fact, was designed at Harvard and MIT originally, uses a system of biological magnets which are contained in small plastic columns. The columns are capable of capturing aflatoxin and only aflatoxin from any food extract and, after a simple washing of the piece of plastic, delivering the aflatoxin in a form that allows its simple measurement in an instrument called a fluorometer.

Dr. Hansen, I think, will demonstrate for you in probably 2 minutes or less, which is the time that it takes to do this test, exactly how it is done.

Tom.

Mr. HANSEN. Thank you.

Mr. GLICKMAN. If you are going to talk, why don't you use the mike, too, so that we can hear what you are doing.

Is there any way to turn that to face us, if you can? The machine? Thank you.

Dr. LIVINGSTON. The key item, I should tell you, is to pay attention to the little window with the number in it. That is going to tell you how much aflatoxin is present in the corn sample that Dr. Hansen is going to test.

Mr. GLICKMAN. Why does it say 012 now?

Dr. LIVINGSTON. The instrument is not standardized yet. When it is standardized, it is going to say zero. Then, after the test is done, it is going to tell you how much aflatoxin is there.

Mr. HANSEN. Thank you, Dr. Livingston.

Mr. Chairman, the fluorometer is a measuring device, because aflatoxin is fluorescent. That is the system that this method uses to measure the amount of aflatoxin present. The real key to the system is the antibody, as Dr. Livingston mentioned, in this plastic column. It is a similar type of technology as the ELISA system, which Mr. Miller mentioned before.

But the combination of the antibody with the fluorometer gives the opportunity of measuring directly the amount of aflatoxin that is in the sample, whether it is 0 parts per billion or 20 or 100. Those of you who saw me when I came in realized that everything that was necessary for the test is contained in the couple of small boxes that I have here.

Mr. GLICKMAN. It doesn't take a mechanical genius to do this test?

Mr. HANSEN. No. I started out with a whole corn sample, grounded. You can grind it in a coffee grinder or in a commercial mill.

I made a dilution from that and actually the steps up to this point are very similar to the ones that are used in the current FGIS screening test.

I get my extract from the corn sample, which I have in here. From this point now, once I apply the extract to the column, it will take just a couple of minutes. I will get a direct reading in parts per billion of the aflatoxin present in that corn sample.

Now, right now, as I load the sample onto the column, the antibodies in the column capture the aflatoxin. I will wash the column to remove nonaflatoxin material.

I don't think I have ever done this in a three-piece suit before.

Mr. GLICKMAN. Do you want to test the peanuts I just ate after you finish that? [Laughter.]

Mr. HANSEN. Now I will remove the aflatoxins from the column with methanol, collect it in a test tube. The test tube is what actually goes into the fluorometer.

I now add a developer reagent, which develops the fluorescence.

Mr. GLICKMAN. In all due respect, he has probably never done this before before television cameras in his life.

What are we doing now? We are waiting——

Mr. HANSEN. Now, we will wait 30 seconds or so and now you get a direct reading in parts per billion of the aflatoxin level in that sample. I chose this sample because I wanted it to be close to the official limit of 20 parts per billion.

Mr. GLICKMAN. Did you calibrate it down to zero before you——

Mr. HANSEN. I calibrated it to both zero and at the high end right at the beginning while Dr. Livingston was introducing me.

Mr. GLICKMAN. OK, because the thing read 11 before you started——

Mr. HANSEN. It read 11 with nothing in the sample chamber. If I put our zero calibration sample, which I had before, that would be zero. This now gives a reading of the actual parts per billion in that ground-up corn sample that I started with this morning.

Mr. GRANDY. Mr. Chairman? Do we know how large the sample is? How large is the sample you are testing? Is it 5 pounds or 10 pounds?

Mr. HANSEN. The actual sample that I tested—I actually brought some corn for the benefit of easterners here—I grew up in Nebraska, so I knew what it looked like.

I prepared this corn sample not from this particular set of whole corn, but I prepared this corn sample before I came down here yesterday. This is a 25-gram sample, but it is a portion of a much larger sample of ground corn.

The actual amount of corn that was taken and ground for the amount that I weighed this out of was probably about 5, 10 pounds.

Mr. VOLKMER. Mr. Chairman, I still have a question. It was 0.11 on there when you started and put it in there. Now, do we subtract that 0.11 from the 0.19?

Dr. LIVINGSTON. No, no, that is an artificial number. It has no standing whatsoever. If you were to standardize the machine with water, it would read zero. So what is on the meter now, Tom?

Mr. GLICKMAN. Nineteen.

Dr. LIVINGSTON. Nineteen. That is how many parts per billion are in——

Mr. GLICKMAN. And that is where it is. We are between 19 and 20. It keeps kind of hedging back and forth between the two.

Dr. LIVINGSTON. And that is 19 with an accuracy of 5 percent, plus or minus.

Mr. GLICKMAN. OK. So this test actually took us about 5 minutes once we did it all. While there appeared to be quite a few steps there, is this a test that an elevator operator could do simply?

Dr. LIVINGSTON. Are doing.

Mr. GLICKMAN. Are doing.

Dr. LIVINGSTON. In significant numbers now. It only requires simple manual manipulations. All of the parts are either plastic or glass and self-marked. All of the instructions are really self-evident.

I think an important point is that no hazardous chemicals are required for its manipulation or its doing.

Mr. GLICKMAN. What is the cost of this particular machine?

Dr. LIVINGSTON. $7.50.

Mr. GLICKMAN. That is the cost of the test. What is the cost of the machine?

Dr. LIVINGSTON. The machine itself varies, depending on the model, but the highest cost would be about $3,000. We are in the process now of looking at machines that cost much less than that. The machine is a one-time-only requirement. The machine has a stand life of at least 10 years.

Mr. GLICKMAN. As I have talked about before, are there comparable machines or competitive machines out that measure aflatoxin to that degree of specificity?

Dr. LIVINGSTON. I can't speak about machines. This is the only quantitative test that I know of that measures aflatoxin with this kind of accuracy in a form in which the weather doesn't make any difference, where you do it doesn't make any difference, and gives you a number. We think a number is important for several reasons.

First of all, it gives the operator flexibility. It tells the person whose corn it is how much aflatoxin is there. Not whether it is more or less than 20 or more or less than 5 or more or less than

some number; it is the actual amount that is there. That may be very important in making decisions concerning the future of that corn.

Second, we think that, in the future, it is likely that the lower the aflatoxin level in corn, the more valuable it is going to be, Mr. Chairman, in the United States and the more valuable we think it may also be in foreign markets.

The only way one can know how much aflatoxin is present, and therefore, look for value-added quality in the corn, is to have a number. This particular method allows one to do that attractively in any reasonable environment.

Mr. GLICKMAN. I think what we will do is we will go ahead and get the other testimony here and then we will ask everyone questions.

I think, Mr. Leonard, you were next on the list. I am sorry, Mr. Stoloff, you are next on the list. Why don't you go ahead, then.

## STATEMENT OF LEONARD STOLOFF, CONSULTANT, SILVER SPRING, MD

Mr. STOLOFF. Thank you, Mr. Chairman.

I have been involved with research on and regulation of aflatoxin since 1963. That was when I was employed by the Food and Drug Administration to direct its first aflatoxin research unit.

I retired in 1982, continued to follow my research interests at a more leisurely pace and have maintained constant and frequent contact with my colleagues at FDA.

In the years with the FDA, I established and maintained a system for collecting and digesting the rapidly growing technical literature on aflatoxins. The system, which is still intact, was soon expanded to all mycotoxins and later to all natural toxicants.

I was responsible for planning and interpreting the results of the aflatoxin or mycotoxin surveillance programs conducted by the FDA field offices since these programs were started in 1967. I was also responsible for the informal coordination of FDA research on aflatoxins and other mycotoxins with academia, industry and other government agencies, a role that was facilitated by my appointment in 1970 as General Referee for Mycotoxins of the Association of Official Analytical Chemists.

The original FDA decision to control the level of aflatoxin in peanuts, and later in other foods, was a prudent action.

Mr. GLICKMAN. I think the record should reflect that we are eating—I haven't yet had the courage to eat the peanuts this morning. I am eating the raisins.

Mr. STOLOFF. You are safe.

Mr. GLICKMAN. Mr. Volkmer is trying it and we will see what happens towards the end of the hearing.

Mr. STOLOFF. To continue, that prudent action was based on the potency of aflatoxin as a liver carcinogen in laboratory rats, and, given the lack of knowledge at that time, the possibility aflatoxin might also be a carcinogen for humans. The action level—that above which legal action against the contaminated commodity would be considered--was set at 20 parts per billion total aflatoxins.

That was the minimum practical level at which the identity of the aflatoxin could be established with the analytical methods available in 1968. That level has no toxicological significance. Confirmation of the identity of the contaminant was needed for a legal case to be made.

As the FDA surveillance program on aflatoxin began to take hold, I started to look for a measure of a public health benefit that should accrue as a result of the reduction of the level of aflatoxin in human food so that continuation of the program could be justified.

I was surprised to find that in the United States, liver cancer, the expected outcome of chronic exposure to aflatoxin, is a relatively rare malignancy. I also observed in the published results of the constantly increasing volume of research on aflatoxin that the strains of laboratory rats used in the original studies were peculiarly sensitive to aflatoxin carcinogenicity and that many species of animals were relatively resistant to its oncogenic effects.

The differences were apparently related to the way each species metabolized aflatoxin. These observations were assembled in a paper that was published in 1976 and I am adding that to the papers that I sent to Mr. Frazier.

In this same period, about 1975, the developing information on the metabolism of aflatoxin by animals, livestock in particular, indicated that aflatoxin was rapidly altered to excretable compounds and that any residues in edible tissue would be but a very small fraction of the amount ingested by the animal.

That information was presented at an international symposium on mycotoxins and published in the proceedings of that symposium, and I am also adding that reprint to the literature given to you.

The data has been recently updated and presented in a paper, together with the rationale used by the FDA, to justify the action guidelines for aflatoxin in animal feedstuffs. That paper was left with Mr. Frazier. That justification included information on the effects of aflatoxin on animal health.

Although liver cancer is a rare malignancy in the United States, there are areas of Africa and Asia where the incidence of liver cancer is very high. To test the thesis that aflatoxin ingestion might be a factor in the occurrence of liver cancer in these areas, a number of epidemiological studies were conducted between 1970 and 1975 under various international auspices.

The resulting data, taken together and at face value, provided a strong presumption that a relation existed between the level of aflatoxin ingestion and the incidence of liver cancer, but a closer examination of each of the published studies revealed serious flaws that cast a doubt over that conclusion.

That conclusion was further weakened by the developing observations from all areas of the world that chronic infection with hepatitis B virus was closely associated with liver cancer. By 1980, the data was strong enough to consider chronic hepatitis B virus infection the primary cause of at least 80 percent of liver cancers.

Chronic hepatitus B virus is endemic in the areas of Africa and Asia where the aflatoxin liver cancer studies had been conducted, confounding the results of these studies, which had not been controlled for that factor.

More important to the deliberations of this committee are the results of an epidemiological study of liver cancer in the United States. I am adding the paper describing those studies to the material sent to Mr. Frazier.

This retrospective study has a much stronger data base than is found in all the studies of Asian and African populations and has no confounding problem with hepatitis B viral infection.

The populations compared are rural, white males in the southeastern States with their counterparts in the north central and western States. There was an approximately 1,000-fold estimated difference in the past exposure of these populations to aflatoxin. I am emphasizing the past because liver cancer now would be created by exposure to aflatoxin 30 to 40 years ago.

The highest exposures were on a par with the highest in the Asian and African studies and of the same magnitude as the lowest level that produced a significant incidence of liver tumors in rats. Therefore, no need for extrapolation, a process which is highly unscientific.

In the face of this past exposure, there is no significant difference in the lifetime risk of liver cancer between the test populations, contrary to what Dr. Tannenbaum suggested was the case in my study. In fact, the highest lifetime risk of liver cancer in the United States is in those populations most likely to be infected with hepatitis B virus: Orientals and urban black males.

The highest risk population in the United States, Chinese males, have a 2.3 percent chance they will die of liver cancer. That is as high as any risk reported elsewhere.

You have been told that the International Agency for Research in Cancer feels there is sufficient evidence to consider aflatoxin a probable human carcinogen. That is the wording of their pronouncement.

This was the conclusion of a working group convened in 1987. I have thoroughly reviewed the evidence cited by the International Agency to support that conclusion. I found the evidence incomplete, some of the evidence incorrectly used, and other evidence employed without apparent critical examination, to the end that the conclusion was not supported by the evidence cited; even though they were a highly esteemed panel.

From all the available evidence, critically examined, I do not see how one can objectively reach any other conclusion than it is highly unlikely aflatoxin is a human carcinogen.

However, there is good epidemiological evidence that aflatoxin is an acute hepatotoxin for humans—that evidence is strong—and should be regulated as such in foods.

Aflatoxin is also an acute toxin for livestock and FDA action guidelines for aflatoxin in feed, as previously noted, take that information into account. Rationales for responsible regulation of aflatoxin have been published and those papers have been submitted to Mr. Frazier.

Thank you.

[The prepared statement of Mr. Stoloff appears at the conclusion of the hearing.]

Mr. GLICKMAN. Before I go to Mr. Leonard, could you briefly explain what a hepatotoxin is.

Mr. STOLOFF. A hepatotoxin is a toxin for the liver.

Mr. GLICKMAN. So what you are saying is that it hurts the liver, but it doesn't necessarily cause cancer of the liver.

Mr. STOLOFF. That is correct. It would be the same as acute hepatitis. The result has been described as toxic hepatitis.

Mr. GLICKMAN. In your professional opinion, aflatoxin would cause hepatitis, maybe, but just not cancer of the liver?

Mr. STOLOFF. That is correct.

Mr. GLICKMAN. I realize the question is not a very scientifically phrased question and we will go back and get your views on this, but I just wanted to get that for the record.

Mr. Leonard, it is a pleasure to have you here.

## STATEMENT OF RODNEY E. LEONARD, EXECUTIVE DIRECTOR, COMMUNITY NUTRITION INSTITUTE

Mr. LEONARD. Thank you, Mr. Chairman. My testimony today will be framed in the reference to a 10-year legal battle we have had with the Food and Drug Administration over its regulatory policy relating to aflatoxin.

In 1980, we began—1979, actually—we began an effort to track what FDA was doing in relation to aflatoxin and although the agency insisted that it was taking steps at the time to reduce the level of exposure in the United States, what we found, in fact, was that although the allowable level, as Dr. Stoloff indicated, was 20 parts per billion, that, in fact, the agency was routinely authorizing the shipment of corn across State lines at greater levels than that.

This is rather interesting because it is the first time I have heard the FDA, or a former FDA person, acknowledge that 20 parts per billion has no toxicology basis, that it is really a reference to the capacity to measure.

We based our legal steps on the Food, Drug and Cosmetic Act, which says that:

> The FDA shall promulgate regulations limiting the quantity of unavoidable contaminants to such an extent as the Secretary finds necessary to protect public health.

Needless to say, after 7 years in the courts, what turned out was that what we thought was very clear language in the law, the Supreme Court determined was ambiguous. However, the courts did say that what FDA was doing by privately allowing States to ship grain across State lines was, in fact, protecting the shippers from any kind of Federal regulatory action. Before the agency could do this, they had to hold public hearings, or at least publish their intent to do this and allow public comment.

After we succeeded at least in gaining that legal status, the Food and Drug Administration, in relation to the current outbreak of aflatoxin, said that they would not use action levels; henceforth, they would simply provide guidelines which would indicate that if the agency decides to take legal action, it would take legal action based on those figures.

The thing that concerned us most is that the agency has pointedly declined to ask for public comments since the guidelines are not considered to be official actions.

In effect, the agency continues to shield itself from public scrutiny by withholding the data on which the standards are based. Therefore, the public cannot evaluate whether the research is adequate to support FDA's position or that the risks to health are greater than FDA should permit.

Thus, our 7-year legal battle has provided us a number of conclusions and offered some opportunities for new directions.

First, a regulatory agency, unless Congress is very explicit as to what it expects, will always do as it pleases.

Second, the law and regulation on unavoidable contaminants dictates essentially that if any legal step is taken to protect the public, it is always going to be too late because an outbreak will have occurred.

Third, aflatoxin outbreaks occur regularly in the United States, at least 2 to 3 times every decade.

Fourth, FDA does not want to reveal the risk assumptions it is using in setting present standards. In the case of milk, for example, FDA allows up to one-half parts per billion, while other countries, including the European community, have set the maximum at 0.05 parts per billion. The EC, in addition, is considering steps to bring that maximum down even further towards 0.01 parts per billion, primarily because the 0.05 parts per billion level assumes a maximum risk of 50 additional cancer deaths per million population over a lifetime. That suggests the level of 0.5 corresponds to a 500-in-1,000,000 lifetime cancer deaths.

We have asked FDA to state publicly the lifetime risk of cancer and I have attached a letter to my testimony outlining that request.

Fifth, other countries, particularly those that import grain, are rapidly developing tolerance levels for aflatoxin in animal feeds and food. The EC has lowered the allowable level of aflatoxin in feed for milk cows to 10 parts per billion, half the current U.S. standard, and has established 200 parts per billion, or 100 parts per billion under the current U.S. standard.

Twenty-two countries in 1980–81 had standards for animal feeds; 35 had those standards by 1986. Some 50 countries have aflatoxin regulations now for food, and of those, 14 have specifically set up tolerances for milk. Those numbers can be expected to come down and the number of countries establishing tolerances can be expected to increase, particularly as consumers begin to understand the substantial risk to health that is involved.

The pattern has implications not only for health, but also for U.S. agriculture because if the world market becomes concerned about the quality of U.S. grain and the way that we handle aflatoxin, we are going to have to compete with other countries that may be offering cleaner grain than we are willing to provide.

We have already seen that pattern develop this year in relation to the corn crop with the EC, the Soviet Union, and Japan, where they all have standards that are much tighter than what we apply here in the United States and I don't think American consumers are going to accept second best for very long.

I think a problem with aflatoxin is that—and with other problems relating to mycotoxins—is that rather than trying to regulate after the fact, we should focus more on prevention. That is, we

ought to look at harvesting techniques and technologies and to evaluate their effect on aflatoxin contamination. We ought to begin developing a method to detoxify aflatoxin. We ought to develop a better network of testing facilities. We ought to lower our standards over a specified period of time. We ought to prohibit the mixing of grain, of clean grain with aflatoxin-contaminated grain, and we ought to ensure that the standards applied at the Federal level should also apply within a State; and finally, we ought to, over a specified period of time, 5 years perhaps, develop lower and lower standards of aflatoxin.

I thank you very much for the opportunity to present testimony.

[The prepared statement of Mr. Leonard appears at the conclusion of the hearing.]

Mr. GLICKMAN. Thank you.

Let me just try to clarify for the record. Dr. Tannenbaum and Dr. Livingston, you have heard Mr. Stoloff's comments about the fact that aflatoxin—the working group was not correct in terms of aflatoxin being a carcinogenic substance. I think he said it had other deleterious effects, but not cancer-causing.

I wonder if you would comment on that.

Mr. TANNENBAUM. I would be happy to, Mr. Chairman.

However, I think it would not be very productive for us to get into a battle over this right now because what is at issue here is scientific facts.

Let me say, however, that Dr. Stoloff's viewpoint is somewhat unique, and I don't believe it is widely held at all in the scientific community or in the medical community.

I think what you have to understand is that the IARC working group that arrived at that conclusion arrives at that as sort of a consensus document. The consensus is very strong. I think if you look at—I won't go through the list of people that were involved in that. They are fairly distinguished members of the scientific and medical communities from around the world.

The document deals with the issues that are raised by Dr. Stoloff, such as the question of the compounding effects of hepatitis B virus and I just don't think there is any question.

As I said before, the decisions of this group are so conservative that this is still the only compound, food-borne compound, that has been deemed to be a human carcinogen. I mean, this compound is unique in that respect.

I think that there is another point that needs to be dealt with here which is quite important, and I agree that the 20-parts-per-billion standard was not set for toxicological reasons; it was set because at that time, the technology of testing was capable of only dealing with 20 parts per billion. In fact, aflatoxin is regulated as an adventitious contaminant of the food supply.

I don't think there is anyone who would argue in the Food and Drug Administration that it would not be desirable to eliminate it. This is present in a lot of public testimony, going back for many years, including extensive comments by Richard Merrill, who was then Chief General Counsel of the FDA. In 1978, when the FDA wanted to lower the standard from 20 parts per billion to 15 parts per billion, a lot of testimony was published in the Federal Register dealing with the risks, and I think there is no question but that if

we could get it out of the food supply completely, it would be desirable and there would be a health benefit.

Now, I don't think that that means that there is an imminent health danger in this country, and I think there were some comments made before which I think need perhaps some edification. Aflatoxin, as is typical for most carcinogens of this type, only bring about their effect at low concentrations when you are exposed to them over a long period of time. I mean, this is a sort of lifetime exposure problem. A single dose or a single bad year is not going to have the effect of making people drop in the streets.

However, I think what we need to—and the reason that milk is such an important commodity is because our children are the biggest consumers of milk. The reason we have a lower standard for milk than we do for corn is for that reason. So I think it is generally understood by people that have made these regulations that there is a health benefit to lowering the amount in all parts of the food supply.

I think that the only way we are going to be able to do that is to increase our surveillance of the——

Mr. GLICKMAN. Before Mr. Stoloff responds, let me ask you another question.

Do you see—again, these epidemiological studies—I suppose they are difficult because if the aflatoxin was just discovered in the early 1960's, it may not present enough time to do long-term studies, but I know back in the 1930's, we experienced a very serious drought in this country, a repetitive drought.

I don't know how we stored corn back then, but one would assume that aflatoxin has been around since time immemorial. It is just that we haven't found it. As I understand it, you discovered it. Somebody here, or somebody——

Mr. TANNENBAUM. No. My colleague of 30 years, Dr. Wogan.

Mr. GLICKMAN. Who I met, I think.

Mr. TANNENBAUM. Right.

Mr. GLICKMAN. Do we have any reason, any epidemiological studies at all to show yes or no yet, or is it just too soon?

Mr. TANNENBAUM. I think that—again, I don't want to reiterate everything that is in this document, but I think in this country, we happen to be very fortunate in that both the Food and Drug Administration and the Federal Grain Inspection Service, I think, have done an excellent job, in fact, in protecting our food supply.

In addition, I think that as was commented before by Mr. Miller, I think that the agri-industrial food complex has done an excellent job of monitoring the product, the raw material that is coming into their plants. I think I have cited the peanut industry as a superb example of how levels have been kept down in most peanut products well below 5 parts per billion.

So I think it is possible to do this.

Mr. GLICKMAN. Is liver cancer the only cancer that aflatoxin is—at least the studies show—that——

Mr. TANNENBAUM. We don't really know exactly which cancers. I mean, if we look at animal studies, which is the only way we can make these sorts of predictions, I think that there is evidence for cancer of the gall bladder, of the bile duct, of types of bone cancer. I think that these perhaps need to be considered.

The aflatoxin may not be the only cause of those cancers. I think aflatoxin may not be the only cause of liver cancer. These epidemiological studies are extremely difficult to interpret. That is why many of them are done. That is why we have to look at countries where, unfortunately, in Africa and Asia, I think they have much more severe problems of contamination than we have in the United States, and that is where you find these higher rates.

Mr. GLICKMAN. OK.

Mr. Stoloff.

Mr. STOLOFF. First, the animal studies show liver cancer before they show anything else. The cancers of other organs were produced in animals under extreme conditions only and always in conjunction with liver cancer. So if you are talking about chronic exposure to aflatoxin, you are talking liver cancer and only liver cancer.

As far as whether we have been exposed to aflatoxin for a long enough time to see something, aflatoxin has been with us before we even knew the name. There is evidence from the veterinary records of moldy corn toxicoses with the symptoms of aflatoxicosis—that was before we had the word aflatoxin—in the U.S. Southeast.

The epidemiological study that I carried out determined that the type of corn grown in the Southeast in the days before we had hybrids was just as susceptible to invasion by *Aspergillus flavus* and production of aflatoxin as the hybrids that are being grown now. I went through that thoroughly to make sure that we weren't missing something.

The record of mortality from liver cancer was an 8-year record that was developed by the Center for Health Statistics. It was a complete record on computer tape for the entire country, including liver cancer in the Southeast. I cued in on males, and I cued in on the rural population because there we have a stable population, and I cued in on white males because then we could make comparisons across the country.

We had a good, stable population. The Southeast white males were exposed to aflatoxin at levels as high as any reported from Africa and Asia. The consumption of cornmeal and corn grits, as you well know, is very considerable in the U.S. Southeast, particularly in the rural areas, and they prefer their corn grits full-fat. Full-fat corn grits has all the aflatoxin in the original corn. Normally, milling of corn, including removal of the germ, removes a considerable portion of the aflatoxin.

The exposure to aflatoxin in the Southest resulted in only a 6 percent excess of mortality, lifetime risk of liver cancer, in that population over the rest of the population, and 6 percent in an epidemiological study is nothing. It is zero.

Mr. GLICKMAN. Let me ask you. You mentioned the question of hybrids. Do some corns—are some corns more susceptible to aflatoxin than others? With all the changes in the hybrid production of corn, does anybody have—we didn't ask Mr. Miller this—does anybody here know that?

Mr. STOLOFF. There were some studies claiming that there are differences, but in the studies we did that used a number of different hybrids plus several of the original open pollinated varieties that were used before then, all had the same susceptibility to afla-

toxin contamination. These were grown in experimental plots, side by side.

Mr. GLICKMAN. Final question and then I am going to yield to my colleagues.

This machine that you have shown right here, which is used by some elevators and other places are using it, does the FDA—does the FGIS currently recognize this as acceptable testing?

Dr. LIVINGSTON. It is currently under investigation by the FGIS.

Mr. GLICKMAN. OK. Now, what else is out there?

Dr. LIVINGSTON. There are a series of tests which use the method described by Mr. Miller as ELISA, enzyme-linked immunoabsorption assay, in which one gets a color readout as a result of an immunological reaction, a reaction between a protein called an antibody and aflatoxin. That can occur in a variety of ways. A commonly used method of that type gives an impression of whether or not there is or are not 20 parts per billion in one's corn.

Mr. GLICKMAN. Is the intensity of the color somehow related to how much——

Dr. LIVINGSTON. There is also a test which allows one to determine the amount of aflatoxin present based on the intensity of the color.

Mr. GLICKMAN. Now, are these methods being used by elevators out there, the color testing and that kind of thing?

Dr. LIVINGSTON. I think that these methods are also being used in the field.

Mr. GLICKMAN. All right.

Mr. Penny.

Mr. PENNY. Thank you, Mr. Chairman.

Mr. Leonard, you remarked that you were concerned about the level of mixing between grain that was infected with aflatoxin and grain that was not. But I don't recall you mentioning what you felt our policies ought to be or our procedures ought to be to deal with that mechanically. Once we find out that we have aflatoxin, how would you recommend that the FDA or the FGIS monitor that grain to stop further mixing?

Mr. LEONARD. First of all, they should simply prohibit——

Mr. PENNY. Prohibit it from being used at all? We heard testimony earlier that it could be used safely in other ways. Oh, mixing.

Mr. LEONARD. No mixing. They ought to prohibit the mixing or commingling of the corn to bring it down to the safe—or the levels that FDA says are safe for their uses. That would simply mean that they would have to segregate the corn that exceeds the action levels or tolerance levels or guideline levels, whatever terminology you want to use.

Then we will have to determine some way to use that corn to protect the public health from exposure to it. Part of the problem now is that we do not have any effective detoxification methods. There are a number of methods, mainly ammoniation, that are being proposed, but there is no proof that that really removes the toxic element of the compound.

The problem that we are dealing with here is that we always treat these situations as an emergency. They occur regularly. We know that they are going to come. As soon as we know that we

have a drought condition, we can predict that we are going to have an increase in aflatoxin somewhere in the grain supply.

The problem is that we ought to be ready to deal with that. We ought to be doing research, federally funded research to develop a detoxification method. We ought to be spending more money on doing testing and on setting up a network of test sites.

There is no reason why we can't have very quick, simple tests. There is no reason to test grain by shipping samples off and three weeks later, getting the results back.

Mr. PENNY. Do you have any strong feeling about whether those tests ought to be conducted by private interests or government agencies?

Mr. LEONARD. I think the most important thing is that there be a testing protocol that applies both to private and to Federal so that——

Mr. PENNY. The testing standards would be the same——

Mr. LEONARD. Testing standards would be——

Mr. PENNY [continuing]. And if they are privately tested, they just have to certify the results, and that would be satisfactory. You are not recommending that we greatly broaden the responsibility of——

Mr. LEONARD. Not recommending.

No, I don't think we need to set up a great big Federal system. I think that the private system—there is a private system in place, obviously. The larger companies already are testing to try to prevent contaminated corn from entering their product lines.

But generally, we don't have that across the board. We don't have a requirement that it be tested. We don't have a requirement, for example, that all milk be tested so that we know that our milk supply is not only safe in regard to the biological contaminants, the bacteria, but also mycotoxins.

Mr. PENNY. Again, I may have missed this in your testimony, but your view, then, is that we ought to have a routine testing of all grain shipments or of all grain deliveries, instead of, right now, a system in which certain firms test for their own purposes and certain elevators test during those seasons in which we feel we have a greater risk.

You are saying year-in and year-out, we ought to have a more routine process of testing?

Mr. LEONARD. I think we obviously have to try to get the testing down as close to the harvest as we can because, as was pointed out by Mr. Miller, once the grain begins to be accumulated in elevators, you are already mixing——

Mr. PENNY. The mixing occurs.

Mr. LEONARD. Mixing is already occurring.

Mr. PENNY. Does anyone at the panel table have any direct knowledge of our food AID shipments and how they are handled?

[No response.]

Mr. PENNY. No one here does. I will have to pursue that with the FDA.

Mr. LEONARD. I know that some of the AID shipments—some of the AID shipments are tested because we have had calls from firms that were involved in some of those shipments where the country receiving the grain did test it for aflatoxin and discovered that it

was heavily contaminated and turned it back. But that is fairly rare.

Mr. PENNY. That was something that occurred to me and which we do have certain nations which, on a very regular basis, are, we hope, benefiting from those shipments, but I wasn't really sure whether we had a policy of testing for aflatoxin before those shipments went out.

Mr. LEONARD. We do not. The United States does not—AID does not have a requirement that grain be tested for aflatoxin.

Mr. PENNY. Does anyone at this table have any experience with imported grain, grain that we receive from other nations? We had testimony from FGIS that we do not routinely check any grain coming in. We assume that FDA will catch it when it goes into the food-production chain.

I would assume, though, that your feeling about domestic testing being routine would apply as well to our policy toward imported grain, to make sure that we are being protected from any of that contaminated grain coming in.

Mr. LEONARD. Absolutely.

Mr. PENNY. Mr. Chairman, I don't have any further questions of this panel.

Thank you.

Mr. GLICKMAN. Thank you.

Mr. Jontz.

Mr. JONTZ. Thank you, Mr. Chairman.

I want to begin by thanking all of the witnesses. It has been a very, very helpful panel.

Let me see if my understanding of the nature of the problem that you see is correct. First of all, there is agreement that the present level of 20 parts per billion was set arbitrarily because of the detection abilities which have long been eclipsed by modern technology.

It is the recommendation of all of you, except for Dr. Stoloff, that our standards be reviewed in light of current evidence and current understanding to ensure that the action levels are based on what we now know about the effects of aflatoxin or is that an incorrect understanding?

Mr. TANNENBAUM. You are dealing, Mr. Jontz, with a very complicated question. I mean, we are not here really today to discuss what the action level should be, which I think has to do with acceptance of a testing methodology and has some legal issues associated with it. I think that the Food and Drug Administration should be represented here if we are going to discuss this issue because they are the agency that is mandated to meet these standards.

There are many different laws and regulations that govern levels, including whether interstate shipment is going to take place or—in which case, it doesn't matter whether it gets into food or animal feed, but also whether it gets into the food supply.

I think that, as I said before, the food industry—the food industry has tried very hard to get the levels down much lower than the action level of 20 parts per billion. I think they have been fairly successful.

Mr. JONTZ. OK. So there is some agreement, then, that—without getting into the question this morning—and I appreciate that fact

that it is not in the jurisdiction of our committee—it is the responsibility of FDA—as to what the standards are.

There is general agreement that meeting lower standards is desirable.

Dr. LIVINGSTON. Not a problem, I think, is a better way to put it.

Mr. JONTZ. It is not a problem; it is possible.

Mr. Leonard wants to disagree, I think, so far as the standards question. Am I wrong?

Mr. LEONARD. I simply want to suggest that—I brought along a couple of papers that were prepared by the Food and Agriculture Organization and by the World Health Organization, which simply list the current standards that are being used by countries around the world.

What we are into now is a situation where there is going to be a horse race to see who develops the lowest and the best standards. We have to deal now with this as an international issue to develop a worldwide standard for mycotoxins so we don't get ourselves caught or mouse-trapped in a trade barrier.

Mr. JONTZ. OK.

Let me put it this way, the evidence that is out there accumulates slowly because of the latency of the period that is involved. We know enough to reach the conclusion that we ought to be trying to meet stricter standards than the 20 parts per billion and that we can do that. Is that correct?

Dr. Stoloff, do you want to get in on this?

Mr. STOLOFF. Before you set a standard, you have to have a risk analysis, and you have to make a determination of whether or not aflatoxin is a human carcinogen. That has to be settled before you can set any limit.

Mr. JONTZ. Apparently it wasn't—apparently that is not where the 20 parts per billion came from.

Mr. STOLOFF. A standard can be set on the basis that aflatoxin is an acute toxin for humans, which is definitely established——

Mr. JONTZ. Yes.

Mr. STOLOFF. I have made some recommendations in the paper that was submitted to the committee. Those limits were based upon the frequency distribution of aflatoxin in the major crops susceptible to aflatoxin contamination, peanuts and corn.

Other crops, you can forget about. The amount and level of contamination are insignificant, compared to corn and peanuts.

Using the point at which you could utilize the major portion of the crop in the areas where you have the major contamination; that is, corn in the Southeast. If you set a level of 100 parts per billion for aflatoxin in corn, you would be safe from any of the acute effects at any level that humans are eating it. It would also be safe for animals.

If you want a means of destroying aflatoxin, feeding it to beef cattle is the fastest way of getting rid of it. They metabolize it extremely rapidly and excrete it rapidly.

Mr. JONTZ. There is some difference, obviously, among the panel members on this question.

Dr. Tannenbaum's statement, if I recall correctly, is that aflatoxin is a recurring problem under different circumstances, different time periods. To suggest it is a problem only in corn in the

Southeast or only in corn in the Midwest because of the drought is—this is a point on which you differ. That will be resolved today.

Let me move on and ask a second question, if I could. Dr. Tannenbaum, you have advised, and Dr. Livingston, that we could learn quite a bit from a review of the efforts by the peanut industry to deal with the aflatoxin problem and, if I understand your recommendation correctly, one, you feel that steps can be taken by corn producers relating to the way that corn is stored and processed, et cetera, that can reduce the incidence or danger of aflatoxin; and two, that you believe that a surveillance system that is more thorough can be devised.

Now, there are a lot fewer peanut producers in this country than there are corn producers so we are talking about a different scope, but is that a fair summary and where would you suggest we go from here in terms of—who should have responsibility—where should we proceed from here in terms of taking the lessons of the peanut industry and applying them to the problem of aflatoxin in corn?

Mr. TANNENBAUM. You have asked some complicated questions, but I think that—generally I think I agree with your summary of the situation. Let me explain one simple fact about what is common between aflatoxin contamination in corn and in peanuts.

You have—it is a sporadic—even in a crop that is contaminated, it is a sporadic event. One in 5,000 peanuts may be contaminated. One in several thousand grains of corn may be contaminated. It is blending that—you may have large numbers of lots of corn—I mean, this is known for peanuts—that aren't contaminated at all. All right.

So, if you can catch the contamination as early as possible, which is what is done in the peanut industry—I mean, I am not saying that what they are doing in the peanut industry, obviously, is going to work exactly for the corn industry. I have never—I eat corn, but I don't grow it.

I am very happy to leave it to the Federal Grain Inspection Service to work out a system. I think that they are quite competent to do this. But I think that what is needed is increased testing because the more lots that you test, the more you are going to be able to pull out earlier the contaminated material and remove it from the supply.

Mr. GLICKMAN. Would the gentleman yield just for one second on that point?

Mr. JONTZ. Sure.

Mr. GLICKMAN. I want to get this clear, because we were talking about this before.

The way this thing becomes contaminated is because the spores move from kernel to kernel? I mean, what I am trying to figure out is if you have blending of contaminated versus uncontaminated corn, not only are you bringing in the corn that has been contaminated, but the likelihood that it will further contaminate as it expands and augments——

Mr. TANNENBAUM. Yes. There are two things that happen. One is that kernels that are already contaminated will, if stored under unfavorable conditions, will produce more toxin, so you will have more toxin per kernel.

The second is what you stated before, Mr. Chairman, that spores will then be produced and kernels which were not contaminated will become contaminated. So the problem becomes exacerbated.

Mr. JONTZ. So test early, test thoroughly and don't—segregate. Don't follow this mixing policy that, well, the grain is already in New Orleans, so we are going to have to mix it with something else. You disagree with that policy?

Mr. TANNENBAUM. I think from a purely economic point of view, you want to test as early as possible. You want to test it before it gets into the original silo. Then I think that you will wind up having, as you do with peanuts, an added-value system where corn that has lower aflatoxin will have greater value.

Mr. PENNY. Mr. Chairman, if I could follow up on that point of mixing as well, recognizing that the presence of aflatoxin is influenced by certain conditions, is it also true, then, that if corn contaminated with aflatoxin is mixed with otherwise clean corn or healthy corn, that it will spread into that remaining corn at different rates, depending upon conditions that prevail?

Mr. TANNENBAUM. Right. I mean, if it is stored under conditions where the humidity is low, then I think the problem will not be very serious. However, it is my understanding that in parts of the Midwest this year, due to the fact that we had very unusual conditions where we had alternating spells of very cold periods and then warmer periods with the problems of condensation, so that under those conditions, if there were problems in storage, then the crop that was contaminated will be even more contaminated when it comes out of the silo.

Mr. GLICKMAN. Mr. Penny.

Mr. PENNY. Given those variables, then, there is really no way to have any kind of guarantee once the mixing has occurred.

Mr. TANNENBAUM. I don't think so.

Mr. GLICKMAN. I think Dr. Stoloff wanted to comment on that because I see his head is shaking.

Mr. STOLOFF. Yes, and I will give you a lesson on aflatoxin contamination of peanuts and corn.

The major contaminated of both commodities occurs prior to harvest, in the soil. It occurs under conditions of stress and is occasioned primarily by insect activity. With peanuts, it is mostly termites; with corn, it may be any one of the weevils that damage the kernel and bring the spores along with them, so that the mold will grow in the field before harvest.

In the United States, that is the major source of the contamination. Now, after the grain or the peanuts are harvested, if they are not dried rapidly, there is a chance for any mold that is already there to grow again and, if the mold is *Aspergillus flavus*, produce aflatoxin.

After the kernel is dried to a low-enough moisture, the mold will no longer grow. In fact, the mold may die off, but the aflatoxin is a chemical compound. It stays there and is not changed. Aflatoxin does not recreate itself. It is not a growing organism. It is the product of the growth of the mold——

Mr. GLICKMAN. But if I may stop you, if the conditions are not right in the elevator, the mold can continue to grow and the aflatoxin could continue to increase.

Mr. STOLOFF. That is correct. If the grain is not maintained in a dry state, and if the elevator is not aerated so that you get pockets of moisture, pockets of condensation, you can have further mold growth.

It is not necessarily going to be *Aspergillus flavus;* it could be any one of the other storage molds that are around and then you get other things produced. But then you get a grain that is so moldy that it is no longer salable.

The type of contamination you get under those conditions results in the type of contamination that is highly visible. You get highly visible mold growth, and the FDA makes seizures on that basis alone. They don't have to go testing for any of the other products.

Mr. GLICKMAN. Thank you.

Dr. Livingston.

Dr. LIVINGSTON. Yes. With respect, I would like to make just one point for the record, and that is that the epidemiological argument will undoubtedly go on in the future, and as we all know, epidemiology doesn't prove or really disprove a causal association between any potential effecting agent and a disease.

Nevertheless, I think one should keep in mind the fact that my colleague, Professor Wogin, at MIT, has found that aflatoxin can directly or indirectly induce a specific genetic change in liver cells in living rodents, which is known from studies in humans, to antecede the development of cancer. That genetic change is well-characterized and well worked out and it has been known now for some 7 or 8 years.

I think that is a fact that can't be avoided.

Mr. GLICKMAN. We thank you for your testimony today. This has been fascinating and interesting. I hope we haven't shown our ignorance on the panel in terms of our ability to perhaps not be as versed in scientific and chemical issues, but I do think that the testimony is very useful and relevant.

Dr. Stoloff, we appreciate your providing another side of this issue which will be important as we examine the record.

Thank you, all, very much.

The last panel today is the panel basically from the National Grain and Feed Association, but it is Mr. Lyle Kuhlmann, president of Byron Elevators, in Byron, Minnesota; Mr. Jim Rutledge, vice president for food protection services, with Bunge; accompanied by Mr. Randy Gordon; and Mr. Kyd Brenner, director of public affairs, Corn Refiners Association.

I know that Mr. Kuhlmann is from Mr. Penny's district and so I am going to turn it over to Mr. Penny to make a few remarks.

Mr. PENNY. I thank you, Mr. Chairman.

I want to welcome all the members of this panel, and in particular, I want my colleagues to know of Lyle Kuhlmann and his leadership in this area. In my judgment, there isn't anyone better able to speak to these and related issues than Lyle. He and his family have run an elevator in Byron, Minnesota, for a good number of years. I have gotten to know them in the time that I have been in public service and they are outstanding local business people, they have maintained a close relationship with their customers over the years and are an example of the best kind of elevator service that is available in this nation.

It is fully fitting, in my judgment, that Lyle should be in a leadership position with the National Grain and Feed Association, because he really, through his own operation back in Byron, Minnesota, tries to excel in every way and set an example for the industry. We are glad to have him here to present testimony on behalf of the National Grain and Feed Association this morning.

Mr. GLICKMAN. Thank you, Mr. Penny.

Why don't we proceed. I think, Mr. Kuhlmann, you are first on the agenda, so we will start with you.

We apologize for taking so long, but this is a complicated issue. We want to make sure we understand it as best as we can.

Let me restate that all your statements will appear in the record in their entirety, so if you wish to summarize to give more chance for questions, that would be fine with us as well.

Why don't you proceed?

## STATEMENT OF LYLE S. KUHLMANN, PRESIDENT, BYRON ELEVATORS CO., ON BEHALF OF THE NATIONAL GRAIN AND FEED ASSOCIATION

Mr. KUHLMANN. Thank you, Mr. Chairman, and Mr. Penny, and members of this subcommittee.

I am Lyle Kuhlmann, president of the Byron Elevator Company, chairman of the National Grain and Feed Association's Feed Industry Committee, and immediate past chairman of its country Elevator Committee.

Appearing with me is James Rutledge, vice president of food protection services for the Lauhoff Grain Company, Danville, Illinois.

We are accompanied by Randall C. Gordon, vice president, communications and government relations for the NGFA. It is on behalf of its 1,350 member companies of the NGFA, representing country elevators, feed mills, terminal elevators, grain processors and exporters, that we testify today.

We welcome this opportunity to share with the Congress the kinds of safeguards and checkpoints that exist in the grain and feed distribution system to ensure that the U.S. consumer and our export customers receive a wholesome and safe food and feed supply.

Let me make two observations at the outset. First, our industry considers aflatoxin to be a serious matter, and places a great deal of emphasis on detecting and keeping it out of the food and feed supply.

Second, aflatoxin is not a perennial or pervasive problem, occurring only during years with extreme weather conditions. We have coexisted with aflatoxin for years and are well aware and share the concerns it raises. Our industry reacts quite dramatically when weather conditions are conducive to aflatoxin development.

This year, similar to other years with aflatoxin concerns, the NGFA has been active in working with the FDA and the FGIS. Such open dialogue fosters a better understanding among the agencies and the industry of the nature of the crop situations and the implementation of proper procedures to detect and keep violative levels out of the food and feed supply.

My point is, with the immediate dissemination of information on aflatoxin during problem years, it is virtually impossible not to be aware of the problem. In areas where aflatoxin is suspected, action is taken to determine the extent of the problem while the corn is still on the stock. Next, as a practical matter, it is common for country elevator managers to test incoming shipments for aflatoxin.

An informal survey conducted by the NGFA on manufacturers of four of the more popular aflatoxin quick-tests found that more than 400,000 tests were sold during the 1988 harvest. This is in addition to the use of the black light testing that has become routine at elevators in affected areas.

Powerful economic forces discourage elevators from handling corn contaminated with aflatoxin. They risk having the contents of their entire elevator seized and condemned if they ship corn containing violative aflatoxin levels.

Further, buyers' purchase contracts typically contain clauses that allow them to reject a shipment at destination at considerable expense to the shipping elevator. That is especially true of the destination in the market area that has no approved use for the corn.

Perhaps I can best illustrate by reviewing the response of my own firm to the reports incidence of aflatoxin in the 1988 crop. When it became clear that the drought could foster aflatoxin, our two State grain and feed associations joined forces with the University of Minnesota Extension aflatoxin specialists to conduct three informal workshops. A fourth seminar was conducted by the Southeast Grain and Feed Dealers Association of Minnesota.

Those workshops provided education upon proper sampling, testing and safety procedures. Ultimately, the University of Minnesota conducted 12 such seminars with industry and producer groups. Separate meetings were conducted with voc-ag teachers and all the county extension agents. There were over 350 elevator managers and operators at these meetings.

At my elevator and feed mill in Byron, Minnesota, we worked with our producer customers to examine the 1988 crop prior to harvest. We performed field tests with farmers in the suspect areas. Even though we did not find any aflatoxin in the growing crop in our immediate market area, our company adopted a policy of using only 1987 crop corn in our local shipments and feed mill rations for one month after the harvest began until we were assured that the new crop corn we were receiving was safe.

Incoming grain from the farm was black-lighted. Any suspect samples were tested with quick-cards. No samples were found to contain aflatoxin. Despite this, we screened all incoming corn to remove broken kernels and foreign material prior to storage, since we have been advised that these particles in the broken corn are more susceptible to aflatoxin than the whole kernel.

The same procedure was followed on our outbound shipments. I should note that there is a strong economic incentive to do this, since the market discounts for corn containing more than allowable amounts of foreign material are extremely steep. The corn screenings were diverted to a large cattle feeder for use in beef cattle.

Similar procedures were implemented at many other elevators and feed mills in Minnesota, as well as in States where field tests indicate aflatoxin might be a problem.

Let me now turn to Mr. Rutledge to explain the kinds of procedures used in the dry corn milling industry to safeguard breakfast cereals, mixes, snacks and consumer products.

[The prepared statement of Mr. Kuhlmann appears at the conclusion of the hearing.]

STATEMENT OF JAMES RUTLEDGE, VICE PRESIDENT, FOOD PROTECTION SERVICES, LAUHOFF GRAIN CO., ON BEHALF OF THE NATIONAL GRAIN AND FEED ASSOCIATION, ACCOMPANIED BY RANDY GORDON, VICE PRESIDENT, GOVERNMENT AFFAIRS AND COMMUNICATIONS

Mr. RUTLEDGE. Mr. Chairman, Mr. Penny, I, too, appreciate the opportunity to appear before you to address this important subject of aflatoxins in corn and corn products.

My name is James Rutledge. I am vice president of food protection services for Lauhoff Grain Company. Lauhoff Grain Company is a large dry-corn milling firm. We have plants located in east central Illinois and southeastern Nebraska.

We supply milled corn products which are used as ingredients in the manufacture of a variety of human foods, such as breakfast cereals, corn-based snack foods and beer.

Our customers have strict standards of quality concerning the safety of ingredients they purchase. Similarly, we have very strict standards of quality concerning the safety of the ingredients we sell.

My purpose in appearing before this subcommittee is to give assurance that the industry is very much aware of the potential hazards of aflatoxins in corn and that active measures are being taken to guard against levels of aflatoxins in food that could pose a risk to public health. I must speak primarily from the standpoint of what we do at Lauhoff Grain Company.

We began monitoring corn and corn products for aflatoxins back in 1971 and we have continued to do so since that time. The raw material for our milling operations is shelled corn which is delivered to our plants primarily by trucks from a series of country grain elevators. Every in-bound shipment of raw corn is sampled and inspected prior to acceptance into our facilities.

Using large mechanized probes, we take a series of individual samples which make up a composite sample from each truckload. Those composite samples are individually examined under ultraviolet light to detect the typical fluorescence associated with the presence of aflatoxin.

Suspect samples are further analyzed in our laboratories using a test procedure approved by the Association of Official Analytical Chemists. The corn shipments from which the samples were drawn are only accepted if the samples from them test negative for aflatoxins.

To back up our program of rigid examination of in-bound corn, we continuously take samples of our finished corn products and

test them in our laboratories for aflatoxins. That testing verifies the effectiveness of our raw corn inspection program.

If any of our food products did test positive for aflatoxins in our laboratories, we would redirect those products to a nonfood use. Further, we routinely forward product samples to an independent testing laboratory to substantiate our own analytical data.

It may also interest the subcommittee to know, and I think this will help, Mr. Penny, with a question you asked earlier, we do produce corn-based products that are sold to the United States Government for distribution through the PL 480 Food for Peace Program. Those products fall under the inspectional jurisdiction of the U.S. Department of Agriculture's Federal Grain Inspection Service. We have been advised that the Federal Grain Inspection Service laboratory analyzes each shipment for aflatoxins.

To the best of our knowledge, there have not been any positive aflatoxin test results reported for shipments of our products. That represents hundreds of tests by the FGIS laboratory which I think further illustrates the effectiveness of our aflatoxin control efforts.

I hope the statement just given has elevated the degree of confidence the subcommittee has in the efforts being taken to control the potential hazards of aflatoxins in food, and I will turn the testimony back over to Lyle.

[The prepared statement of Mr. Rutledge appears at the conclusion of the hearing.]

Mr. KUHLMANN. As Mr. Rutledge has explained, processors and food companies have extensive quality control programs to detect the presence of aflatoxin long before the products reach the consumer. Likewise, terminal elevators and exporters routinely test incoming and outbound shipments for the presence of aflatoxin.

The reasons are simple. First, most export grain contracts specify the corn shipments contain 20 parts per billion or less, the level considered safe for human consumption. It bears emphasizing that the protections and safeguards in place at export elevators exist for the same reason they do for the producer, the country elevator, the terminal elevator or the feed mill manager, processor or food manufacturer.

In our industry's highly competitive marketplace, a company cannot afford to have its reputation or integrity damaged by reports that it handles or ships corn or corn products that contain illegal levels of aflatoxin.

Our discussion on the safeguards and protections that exist at various stages of the grain marketing and distribution system from the farmer to the consumer is not to say that improvements can't be made. As you heard earlier, FGIS is in the midst of a project designed to meet perhaps the most pressing need, a study that evaluates the performance, accuracy and reliability of a quick, relatively inexpensive test marketed by several manufacturers that are used to detect aflatoxin in grain.

These tests are receiving increased use in our industry and will confirm the use of the black light as a screening method. We commend FGIS for initiating this study and hope it can be completed soon. It is vital any test yield accurate results as simple as possible in the working environment.

Combined with the increased understanding of the environmental conditions that foster mold growth and result in aflatoxin residues, the result of this FGIS study has the potential to further enhance the ability of producers, the grain feed and food industry, to safeguard our food and feed supply.

Mr. Chairman, and members of this subcommittee, we appreciate your time and interest and would be pleased to respond to any questions.

Mr. GLICKMAN. Thank you very much, Mr Kuhlmann.

Mr. Brenner.

## STATEMENT OF KYD D. BRENNER, DIRECTOR OF PUBLIC AFFAIRS, CORN REFINERS ASSOCIATION, INC.

Mr. BRENNER. Thank you very much. Being last on a panel, I have the privilege of having most of my remarks already made by somebody else this morning, so I will try to summarize.

Mr. Chairman, I am Kyd Brenner. I am director of public affairs of the Corn Refiners Association. Our association represents producers of corn sweeteners, corn starches, corn oil, feed ingredients and fuel alcohol. We appreciate the opportunity to be with you today.

As major suppliers of food ingredients, corn refiners are committed to taking every precaution to prevent aflatoxin from finding its way into the Nation's food supply. The presence of aflatoxin is not new; it has been with us since man first harvested crops. We feel this is not a problem that we can hope to legislate out of existence or regulate out of existence. However, we do hope to and can devise effective strategies to deal with it.

As other witnesses have mentioned, our knowledge of aflatoxin dates only to 1960. Beginning in the early 1960's, the corn refining industry began to formulate identification and control programs for aflatoxin. In 1965, we conducted our first crop and product survey for aflatoxin.

In 1966, technical results were published indicating that refined vegetable oil, such as corn oil, processed from deliberately spiked raw material samples were free of aflatoxin contamination.

In 1971, an extensive study done on the possibility of aflatoxin contamination of corn starch was published. Again, this program analyzed both naturally contaminated corn and corn which had been deliberately spiked with high levels of aflatoxin. In all cases, corn starch, from which corn sweeteners are also made, was found to be essentially free of aflatoxin.

Despite these assurances, the industry has still developed guidelines to avoid purchasing corn which does not meet FDA specifications. As has been mentioned, these programs begin well before harvest, monitoring crop conditions so we can identify any areas which may have potential aflatoxin problems.

In all years, the frequency of testing of in-bound corn is increased as new crop corn begins to arrive. This is called for even in years of good crop quality, since aflatoxin may be found in very small localized areas, but not in a substantial portion of the crop itself.

Because 1988 crop conditions were well known before the harvest, refiners were prepared for the new crop. Testing was increased to cover all in-bound corn and the sampling and testing of in-process and finished products was greatly increased.

Three levels of testing of incoming grain are used by the refining industry. A screening test is conducted first and then a minicolumn and/or a chromatographic test are conducted if evidence of aflatoxin is found at any previous step. Depending on the way the grain has been purchased, a positive reading on any of these tests may serve as a basis for rejection of grain.

If the corn is accepted, in-process analysis and final product analysis serve as an additional quality assurance measure.

This program resulted in the rejection of a higher than normal quantity of corn in September and October 1988. It appears that the corn that was in the worst condition was harvested first. Since that time, the rate of rejection has steadily declined. The quality of the crop coming to market is better and the grain industry has made a concerted effort to be sure that corn which does not meet FDA guidelines is not shipped to food companies.

Despite some press reports, the Food and Drug Administration has been very active in surveillance of the food industry for aflatoxin. FDA inspectors have been in many corn-refining plants since last fall.

Changes in the action levels in the feed area have provided a nonfood outlet for grain which is above 20 parts per billion. Finally, USDA drought relief programs have helped eliminate the incentive for farmers to pass contaminated grain up the marketing chain.

Taken together, the efforts of the FDA, the USDA, the grain industry and the corn refining industry are extensive, systematic and more than adequate to ensure the integrity of food ingredients from corn wet milling.

For the future, there are a number of steps we can look at to further our ability to control aflatoxin. Most of them have been mentioned, starting with better, faster and more accurate analytical methods. There is much work under way, including the FGIS tests; and within our industry, we are internally evaluating all of the quick-card methods, the method that you saw this morning, and keeping an eye out for any other potential new methods.

The programs of education on proper screening, handling and storage must continue and be intensified: Breeding research into drought-resistant corn, which could be resistant to mold invasion; the research into potential methods of destruction of aflatoxin, which would be both effective and safe; and finally, I think, and most importantly, we must recognize that aflatoxin does remain an occasional and limited concern and avoid precipitous actions which would cause the public to lose confidence in a safe and abundant supply of corn.

I thank you and also will be glad to answer any questions.

[The prepared statement of Mr. Brenner appears at the conclusion of the hearing.]

Mr. GLICKMAN. Thank you, all, very much for your testimony.

Perhaps this is to Mr. Kuhlman, but maybe for everybody else, what percentage of incoming shipments to country elevators—is

tested for aflatoxin levels? The grain that is brought into the country elevator—is all of it tested or part of it tested? I mean, when I say all of it, is every shipment tested?

Mr. KUHLMANN. Part of it would be tested.

Mr. GLICKMAN. What part? What percentage?

Mr. KUHLMANN. The part that would be tested—first, we did the very early test as the season started to determine if we had a problem. We tested extensively for the first third to half of the season to see—with the black light. It is very easy to use a black light in the screening to check the corn for aflatoxin with a black light.

In areas of Iowa, eastern Iowa, I am familiar with some of the people there and they continued all the time to test all the corn with black light at that time.

Mr. GLICKMAN. So, in your case, because you saw at the beginning there was probably no problem, you wouldn't test every shipment then?

Mr. KUHLMANN. You are right.

Mr. GLICKMAN. Does the——

Mr. PENNY. In most years, though—I mean, last year was an exception and to protect yourself and to protect your ultimate buyer, you tested virtually everything that came in and you did some advance field tests and did an extensive amount of testing.

In normal years, what would you do at the elevator?

Mr. KUHLMANN. In normal years, we start out with a black light and check to see if there is some. The University of Minnesota is quite active in this. They have two people that they have on the Task Force for Aflatoxin all the time. One of those people actually did his thesis on aflatoxin in the storage belt. Aflatoxin corn.

At that time, in the normal year, we will check a substantial amount of the corn as the season begins and if we have problems with the corn that looks suspect, we test that.

Mr. GLICKMAN. But the point is that you will generally predicate your testing for corn based upon your judgment as to whether it is a problem in the area. That is, you won't automatically test all corn that comes in.

Mr. KUHLMANN. No.

Mr. GLICKMAN. Now, the black light is the primary testing that you use?

Mr. KUHLMANN. The first test would be with the black light. We also use a quick-test if we have a positive showing on the black light.

Mr. GLICKMAN. That quick-test is a chemical test?

Mr. KUHLMANN. This happens to be the test right here. This packet does two samples. They come in groups of 20. It takes 10 to 15 minutes to do——

Mr. GLICKMAN. It, by color, shows if aflatoxin is in there?

Mr. KUHLMANN. There is a card that comes along with the test—I guess the card is in the packet here, but there is a card that comes along with the test that you drop the solution on—very much like he made up. You drop it onto the card, onto a spot on the test card and it changes color.

If it changes color, it is above the 20 parts per billion. If it doesn't change color, it is below the 20 parts per billion.

Mr. GLICKMAN. Let me ask you this. Is corn that is used for dairy feed tested more frequently than corn that is used for other feed purposes?

Mr. KUHLMANN. In our case, we use corn all out of the same bin and we don't put any corn into that channel that might contain aflatoxin. The aflatoxin corn that we might have, we would prefer to stop before it comes into the elevator and ask the farmer to find a use for it with his own animals or his neighbors' animals.

Mr. GLICKMAN. OK.

Mr. KUHLMANN. This is pretty much the practice.

Mr. GLICKMAN. Now, again, let me—I am not sure I understood the answer to my question.

What you are saying is that—go back again. The corn that you buy is multiuse corn? I mean, used——

Mr. KUHLMANN. The corn that we bought this past year was aflatoxin-free——

Mr. GLICKMAN. Yes.

Mr. KUHLMANN. So we didn't have the problem of distinguishing between dairy animals and other animals. Dairy animals—the level of aflatoxin in the feed for dairy animals is the same for humans. It has to be below 20 parts per billion.

Mr. GLICKMAN. Yes.

Mr. KUHLMANN. So aflatoxin corn that did—if we did accept aflatoxin corn, it would be used for animals and primarily beef animals because the tolerance is much——

Mr. GLICKMAN. Is higher there.

Mr. KUHLMANN. Right.

Mr. GLICKMAN. So, in your case, there was no special use. Do you know if anybody in the business tests corn, dairy corn, differently?

Mr. GORDON. Mr. Chairman, if I might add, we did some surveys of our members in Wisconsin and other States and they did treat corn that was intended for use in dairy animals the same as they would human food.

Mr. GLICKMAN. OK.

I would ask Mr. Brenner, is the blending of corn—let's see, you blend clean corn with corn contaminated with aflatoxin. Do you think it is an acceptable way to deal with the contaminated corn issue?

Mr. BRENNER. First, from the standpoint of the refining industry, we purchase corn from the grain industry. We are not blenders or merchandisers, I want to make that clear.

To directly answer your question, no, the blending of corn is expressly prohibited, as I understand, by the Food and Drug Administration, except under direct FDA supervision.

Mr. PENNY. Mr. Chairman, again, if I——

Mr. BRENNER. That was a new policy this year.

Mr. GLICKMAN. OK. Yes, Mr. Gordon.

Mr. GORDON. The FDA is very clear in that blending aflatoxin-contaminated corn with clean corn is adulteration under the meaning of the Food, Drug and Cosmetic Act.

Mr. GLICKMAN. So it would be subject to criminal sanction?

Mr. GORDON. That is correct.

Mr. GLICKMAN. So when we were talking before about blending, you could not blend except under specific authority of the FDA?

Mr. BRENNER. Specific and that is new since last September. I think it is very widely known and felt in the industry that blending is an FDA——

Mr. GLICKMAN. I think we need to get, for the record, a statement from the FDA as to what they allow in terms of blending because that issue has been raised by many of us here. I would want to know how and under what circumstances you could blend corn for human, for dairy, for other livestock consumption, as well as for, let's say, nonfood use, as well.

[The information appears at the conclusion of the hearing.]

Mr. BRENNER. I was very surprised at his comments. My conception, and I am sure the conception of the country elevator trade, is that it is illegal to blend.

Mr. GLICKMAN. Illegal to blend.

Mr. BRENNER. Right.

Mr. GORDON. Mr. Chairman, if I could add parenthetically also that under FDA's plan, as Kyd said, this most recent crop year, because of the drought and the lack of corn supply, it is the first year that they have granted an exception to their antiblending policy.

Mr. GLICKMAN. OK.

Mr. PENNY. For what purposes?

Mr. GORDON. The resulting mixture had to be supervised under FDA supervision and—the resulting mixture, regardless of the aflatoxin level—had to be diverted into approved feed use only——

Mr. PENNY. Feed use only.

Mr. GORDON. Or industrial uses. It could not be sent to dairy animals or human food.

Mr. GLICKMAN. It would still be useful to get them here to explain how the blending and under what circumstances it occurred.

Mr. PENNY. I think that is my concern, as well. Because it is impermissible doesn't mean that it is impossible to blend and market. And I am just curious as to how—and maybe somebody here can answer how, the FDA tracks that corn once it is found to be violative of the limits and assures that it isn't blended and marketed?

How do they make sure that that aflatoxin-infected grain is segregated and not blended in some manner?

Mr. GORDON. FDA did have a number of inspectors out sampling corn as it was being delivered by the producer to the country elevator and through spot samples and, again, this well-known policy in our industry that blending is taboo, there is a strong disincentive—the disincentive is economic as well, because there have been cases in the past where FDA has seized the entire contents of the elevator if they have found aflatoxin contamination.

Mr. GLICKMAN. Do you think that it would be useful to have some sort of compensation program, as we did in dairy, for aflatoxin-contaminated corn generally?

Mr. GORDON. Mr. Chairman, this might be something the Congress might want to look at. We have been very supportive of the provision in the drought assistance legislation that allows producers to be compensated for lost production, in effect, on their 1988 crop if it contains aflatoxin. We believe that provides another disincentive to channeling this corn into the marketplace.

Mr. GLICKMAN. Yes.

Mr. PENNY. And it also, under that legislation, provided for that grain to be held off normal market channels——

Mr. GORDON. Exactly.

Mr. PENNY. And so I think that was a protective——

Mr. GLICKMAN. I just want to make one final comment. I appreciate your testimony very much.

It does strike me that this issue, like so many others, cannot be viewed totally in the abstract. It relates to what kind of Farm Program we have, too.

We have had a Farm Program that has encouraged storage because of very, very hefty surpluses. The Government has paid for that kind of storage to take place. A lot of it has been on farms.

I suspect that—and while I don't have the statistics, that there is less aflatoxin in proper storage in commercial storage operations than there is on-farm. What has happened is that through the operation of a program that encouraged that, in light of years of big surpluses, you created additional problems. The aflatoxin problem was probably a side problem that was created from a program that encouraged that kind of storage.

Do you have any comment on that? Mr. Gordon.

Mr. GORDON. Let me start—and our industry witnesses could expound on this more than I, but there are very clear proper storage and aeration procedures that again are well known in the industry that we, our association and our State grain and feed associations and the farm groups dispense widely in years when aflatoxin is a problem concerning the proper drying, aeration and conditioning of grain that helps prevent aflatoxin once grain is in storage.

It is certainly a concern and it is something we look for as it is coming into the elevator system, but the——

Mr. GLICKMAN. But as I said, I think that as a general proposition, commercial storage facilities are generally better equipped to do what needs to be done. I have no reason to believe that you are not doing all that.

I am just saying that legislation, the bill, the way we have domestic farm programs, we have wrestled with how to deal with surpluses and maybe we are over that game for a while, but in the interim period, we have had to deal with storage.

It is just an example of one of the byproducts of a farm policy which has been involved during a surplus era in trying to deal with that surplus when you couldn't get it moved into the marketplace.

So, therefore, we cannot again view this problem in the abstract without looking at the basic Farm Program as well.

Yes, Mr. Kuhlmann.

Mr. KUHLMANN. It might be of interest to you that research work by Dr. Jones at the University of Minnesota is that the aflatoxin is reproduced in stored corn above 16.5 moisture, which is considered as an unstorable level by USDA standards for commodity——

Mr. GLICKMAN. For the CCC elevators that—I mean, for the elevators that USDA has contracts with you on?

Mr. KUHLMANN. Right. And also the temperature—they do not reproduce below 50 degrees temperature and with modern aeration systems, most elevators try to keep their corn at near that level, even into the summer, to reduce the incidence of mold and insects.

Mr. GLICKMAN. Mr. Penny, go ahead.

Mr. PENNY. I was just going to ask Lyle if, in your purchases over the years, recognizing that you haven't really had a problem with aflatoxin levels being very high, have you detected a difference between grain that has been held and stored on farm for some period of time and the levels on grain that may be delivered directly from the field?

Mr. KUHLMANN. Of aflatoxin?

Mr. PENNY. Yes.

Mr. KUHLMANN. We only once have ever had an indication of a black light of corn that was delivered. We had that corn tested beyond, just for our own information, and that corn came out negative. There was no aflatoxin in the corn.

I think where you—in fact, I know that where the case does happen and where corn hasn't been properly aerated and maybe the top foot or so of corn of a grain bin that has been left, the moisture condenses in that area and it heats and this is where the incidence of aflatoxin would happen.

Mr. PENNY. But throughout the rest of the bin, there often——

Mr. KUHLMANN. The rest of the bin wouldn't be affected. It just be that top foot where the moisture level increased and the temperature increased in that bin.

Normally, an elevator sees this corn and they tell the farmer to throw that away——

Mr. PENNY. Throw that part out.

Mr. KUHLMANN. And not to use it.

The one incident in Minnesota of the dumping of milk that was indicated in the Wall Street Journal—there were two incidences—but that particular incident that was called for—the farmer had used grain that was off the top of a bin to make his dairy feed. That milk was dumped.

Another farmer thought he had a problem and he voluntarily dumped the milk. Those are the two incidences that are mentioned in the paper.

My information source is the Minnesota Department of Agriculture on that.

Mr. PENNY. You indicated that except in years where you have weather conditions or whatever that indicate that there may be a problem with aflatoxin, you check basically when you have reason to suspect that there might be a problem with the shipment. Are you looking for the physical evidence of mold, busted kernels, other conditions of the grain that make it a little more susceptible?

Mr. KUHLMANN. What we do is——

Mr. PENNY. On a visual basis, as the shipment comes in, what are you really looking for?

Mr. KUHLMANN. OK. Moldy corn tends to carry more aflatoxin than other corn. What we do is we screen the corn with an 18 screen to determine whether it has any foreign material or broken corn in it. That is the actual corn that we look at under a black light. That would be where the incidence of aflatoxin would be more prominent, in the sample.

So we feel that if we are going to come up with a positive sample and see the fluorescence that it does emit under a black light, that we will be able to recognize it in those conditions. So we do really

check that sample under a better condition than just looking at the whole kernel of corn itself.

Mr. PENNY. And even in those cases where you had a shipment where you were a bit suspicious, how frequently in those instances where, on visible examination, you think that it may be more likely to contain high levels of aflatoxin, how many times do you actually come up with levels that are in excess of the allowable limit?

Mr. KUHLMANN. We didn't see any——

Mr. PENNY. You didn't see any at all, even in those cases?

Mr. KUHLMANN. I would like to give you just the results. The University of Minnesota had their county agents send them in suspect samples. Now, these are not random samples; these are samples where the farmers felt that they had problems.

They tested 52 samples. Of those samples, 14 contained zero parts; 20 contained between 1 and 20 parts; 13 between 20 and 99; 4 between 100 and 300 and one over 300.

All these samples had been screened with a black light prior to sending them to the University of Minnesota. So the incidences, even in a collected sample—and these are just individual cobs that might contain—that you could see that had mold on them, that were tested. They were looking for these cobs so they could use corn that we could identify in the workshops that we might be looking for aflatoxin.

Mr. PENNY. Thank you.

Mr. GLICKMAN. I want to thank you all for your testimony today. This has been a very useful hearing.

I might remind folks that on Thursday at 10 a.m., we will hold a hearing on the 1989 wheat crop. We have another problem with that wheat crop. It is not aflatoxin. There is not any of it. So we will make a judgment as to what to do after that hearing.

The hearing is adjourned.

[Whereupon, at 12:50 p.m., the subcommittee was adjourned, to reconvene at 10 a.m., Thursday, April 6, 1989.]

[Material submitted for inclusion in the record follows:]

TESTIMONY
TO BE DELIVERED BY
W. KIRK MILLER
ADMINISTRATOR
FEDERAL GRAIN INSPECTION SERVICE
UNITED STATES DEPARTMENT OF AGRICULTURE

AT A HEARING OF THE
HOUSE COMMITTEE ON AGRICULTURE
SUBCOMMITTEE ON WHEAT, SOYBEANS, AND FEED GRAINS

APRIL 4, 1989

Good morning Mr. Chairman, ladies and gentlemen. I appreciate the opportunity to discuss the Federal Grain Inspection Service's role as a service organization providing official aflatoxin testing for producers, shippers, and domestic and foreign processors.

## Definition of Aflatoxin

Much concern developed recently regarding a specific mycotoxin known as aflatoxin. Aflatoxin is produced by two types of mold known as Aspergillus flavus and Aspergillus parasiticus. Aspergillus flavus is very common and widespread in nature and is more likely to occur in corn when it is grown under stressful conditions such as drought. It can occur in soil, decaying vegetation, hay, and grains undergoing microbiological deterioration. It can invade all types of organic substrates whenever and wherever the conditions are favorable for its growth. Favorable conditions include high moisture content and high temperature. At least thirteen different types of aflatoxin are produced in nature. Aflatoxin B1 has been regarded as the most toxic.

Types of Analyses

For years FGIS has offered aflatoxin testing services under the auspices of the Agricultural Marketing Act of 1946. The service is provided on an optional, user-fee basis. FGIS provides an ultraviolet light screening test at export locations but plans to replace this technique during the latter part of 1989. In addition, we offer two more definitive types of analysis - the Holaday-Velasco minicolumn and the CB thin-layer chromatography techniques, both approved by the Association of Official Analytical Chemists. The minicolumn is standardized at a specific detection threshold and provides a positive or negative reading measured against a 20 parts per billion standard. It requires approximately 45 minutes to perform the analysis. FGIS charges $22.40 per hour for on-line inspection and $18.90 for individual samples. The thin-layer chromatography analysis provides quantitative results in actual parts per billion. It requires 3-4 hours to complete the analysis. FGIS charges $44.00 per analysis.

The minicolumn and thin-layer chromatography techniques are performed in laboratories by highly trained technicians. While these techniques are sophisticated, they have shortcomings in that they are slow and involve the use of hazardous chemicals. To implement a more rapid test, FGIS began in February of 1988 to evaluate new technologies. Of particular interest is an analysis which is referred to by the acronym ELISA - enzyme-linked immunosorbent assay. This biotechnology-based diagnostic technique is similar to many diagnostic techniques used in clinical

laboratories. Results can be obtained in several minutes at a reasonable cost. It is highly rewarding to FGIS, and to me personally, to bring new technology from other industries to the business of grain inspection in addition to helping FGIS provide better service to its customers - producers, shippers and processors. Our Research and Development Branch, located at the FGIS Quality Assurance and Research Center in Kansas City is evaluating the performance data of the various tests and we expect to announce the results of the evaluation in May.

## Impact of 1988 Drought

The drought conditions in 1988, particularly in certain sections of the corn belt, enhanced the potential for increasing the presence of the Aspergillus flavus mold that produces aflatoxin. To provide maximum service to producers, FGIS briefed the Agricultural Stabilization and Conservation Service and the Federal Crop Insurance Corporation regarding available analytical services. We submitted a briefing paper to the USDA Drought Task Force to alert them to the potential problem. As the drought continued, we expanded the availability of our aflatoxin testing service to meet the expected high demand for service. We increased the number of FGIS laboratories with aflatoxin-testing capabilities and secured the use of the Agricultural Marketing Service's laboratory in Medill, Oklahoma to help test samples, if necessary, during peak demands. By using overnight mail services we have been able to analyze samples from interior locations nationwide and provide next-day service in most cases. The Food and Drug Administration, the regulatory agency with surveillance and enforcement

responsibilities for aflatoxin and other deleterious substances in the food system, issued updated guidelines for safe usage of corn contaminated with aflatoxin.

Depending on the intended end-use, FDA has the following four guidelines that are deemed safe:

0-20 ppb (all uses including unknown destination)

21-100 ppb (breeding cattle and swine, mature poultry, finishing swine, finishing beef cattle)

101-200 ppb (finishing swine, finishing beef cattle)

201-300 ppb (finishing beef cattle)

In response to the new FDA guidelines and increased demand for service FGIS modified a minicolumn procedure for aflatoxin to correlate to each of the FDA guideline levels.

Through a memorandum of understanding, the FDA and FGIS cooperate in the detection and control of grains and oilseeds adulterated, infested, or contaminated with poisonous or deleterious substances including aflatoxin. If officially-sampled grain is tested by FGIS and found to contain aflatoxin in excess of 20 parts per billion, we alert the appropriate FDA district office. FDA provides follow-up action which includes permission to transport and use the corn, if adequate documentation is supplied to verify the intended use of the corn. Other options include seizure by FDA or voluntary destruction.

## Service to Importers

At the onset of the 1988 corn harvest FGIS determined that while we regularly provide aflatoxin testing services for foreign buyers, extra monitoring was necessary to help ensure buyers of the wholesomeness of U.S. corn. On October 24, 1988, FGIS field offices began to inspect and monitor for aflatoxin all shipments of corn destined for Japan, USSR, and Mexico. These countries are important customers of U.S. corn, normally importing large quantities of U.S. corn. During the 1987-88 crop year, for example, those countries purchased approximately 24 million metric tons of U.S. corn. All export corn shipments that FGIS certified for aflatoxin were at or below the FDA guideline of 20 parts per billion.

In calendar year 1987 FGIS conducted aflatoxin analysis on 44% of the total corn tonnage exported that year. This compares to 55% in 1988. Thus far in 1989 we have tested 75% or 9,184,415 metric tons of exported corn for aflatoxin. We reiterate -- of the 1989 export corn tonnage tested for aflatoxin, we have not issued an aflatoxin certificate that exceeds the 20 ppb guideline established by FDA. The results for export corn shipments, however, do not represent a profile of U.S. corn quality nationwide.

## Service Objectives

Through its aflatoxin testing services I believe that FGIS provides producers, shippers and processors with information which enables the

marketplace to operate efficiently and to channel the corn with varying levels of aflatoxin into the safest and most appropriate end uses.

Closing

Mr. Chairman, this concludes my statement. I will be glad to respond to any questions that you or other members of the Committee may have.

The high level of aflatoxin in the 1988 corn crop has raised a level of concern among the public and in the press. I hope that my statement will help provide some perspective on this problem that will help allay public concern but that will also lead to improved measures of control of this problem in the future.

Does aflatoxin contamination of food crops result only from extraordinary weather conditions such as existed in the midwest last summer, so that contamination of corn or other grains is likely to occur infrequently?

It is difficult, if not impossible, to predict when or at what levels aflatoxins are likely to be found in different food crops. The FDA lists the following as crops susceptible to aflatoxin contamination: corn, peanuts, sorghum, rice, wheat, soybeans, walnuts, almonds, pecans, pistachio nuts, brazil nuts, figs, and the edible tissue (meat, eggs, and milk) from food-producing animals that consume animal feed containing these compounds. This is not to say that aflatoxins are always present in these commodities, only that contamination can occur when storage or other conditions permit growth of the toxin-producing fungus, which is ubiquitously distributed. Available evidence, in fact, suggests that both the frequency of contamination and levels of aflatoxins present in different crops show wide geographical and seasonal variations. As a result, the problem tends to be regarded as regional and sporadic in nature. In fact, in prior years emphasis was placed on corn products in the Southeastern United States while this year the problem was more acute in the corn corp in the Midwest. The basic lesson is that the problem can occur anywhere at any time and the only assurance of safety available to us, until we can control the weather, is wider and more frequent surveillance.

Extensive data relevant to this issue are available for peanuts, but less information exists about other crops. Lack of information is due mainly to less extensive surveillance for aflatoxin contamination of the other commodities compared to peanuts and peanut products. Because aflatoxins were originally discovered in peanuts nearly 30 years ago, manufacture of foods and feeds containing peanuts came under intense scrutiny immediately thereafter. In the intervening period, development and application of effective inspection,

storage, sorting and testing procedures have enabled the development of an effective quality assurance component of good manufacturing practice that has made it possible to maintain aflatoxin contamination at levels substantially below action levels set by FDA. In principle, many of these same procedures can be adapted for use with other food crops, and their implementation could similarly protect the food supply from excessive aflatoxin contamination.

The effectiveness of quality control measures in minimizing health risks from aflatoxins is well illustrated by the following. In the early and mid-1960's, liver cancer in hatchery-reared rainbow trout had reached epidemic proportions with serious economic consequences for the hatchery operators. Appearance of the disease coincided with the introduction of a new diet formulation, which contained cottonseed meal as a protein source. In searching for a cause of the disease, it was found that feeding purified aflatoxin to the fish exactly reproduced the cancer, and analysis of the diet identified aflatoxin-contaminated cottonseed meal as the source of the problem. Imposition of specifications requiring monitoring of the meal to exclude aflatoxins resulted in virtual elimination of the disease. This experience illustrates the feasibility of quality control measures, and also represents probably the only natural cancer epidemic to have been brought under control.

How serious a public health problem is aflatoxin contamination of foods?

The concern about aflatoxin contamination is based on their ability to cause cancer, as indicated by a very impressive amount of information about their effects in both experimental animals and people exposed to them. Cancer has been experimentally induced in many animal species, including fish, birds, rats, mice, ferrets, tree-shrews and monkeys by long-term feeding of diets containing aflatoxins at different levels. In the most sensitive species, tumors are caused by dietary levels of 10 ppb or less. Liver cancer is the main form of disease induced by aflatoxins, but cancer of the kidney, colon and bone is also elevated in some experiments.

A second line of evidence of carcinogenic risk from aflatoxins comes from extensive epidemiologic studies of liver cancer incidence in human populations consuming diets contaminated with aflatoxins at different levels. Taken together, results of these studies, conducted mainly in Africa and Asia, show a strong correlation between elevated liver cancer incidence and amount of aflatoxin eaten. The data from various parts of the world, including the US, where aflatoxin intake and liver cancer incidence are relatively low, fit together well. Analysis of the combined human and animal data led the International Agency for Research on Cancer to conclude that the combined evidence was sufficient to designate aflatoxins as human carcinogens, the only food-borne chemicals to be so designated. This IARC document, which resulted from the deliberations of many distinguished scientists, deserves your attention. I am providing a copy for the use of the Subcommittee and its staff.

Thus, the existence of a potential elevation of risk for cancer of the liver, and possibly other organs, from aflatoxin contamination in foods is firmly based on extensive scientific data.

What are the ramifications of not increasing surveillance?

Aflatoxins are extremely toxic to poultry and fish, somewhat toxic to pigs, and cannot be fed to lactating animals. Other countries, notably Europe and Japan, have lowered their standard to 5 ppb or less. If we cannot export contaminated grain, and if it cannot be fed to domestic animals, higher levels of contamination will enter the US food supply to the detriment of our health and that of our children. On the other hand, increased testing of corn in particular will allow segregation of contaminated lots, produce higher quality material for export and lead to lower levels of contamination in the domestic food supply. Let us look at the peanut industry as a positive example of what agro-industry can accomplish through effective quality control.

Remarks on Aflatoxin, Prepared for the House Agriculture Subcomittee on Wheat, Soybeans, and Feed Grains.

I have been involved with research on and regulation of aflatoxin since 1963, when I was employed by the Food and Drug Administration to direct its first aflatoxin research unit, until my retirement in 1982. In the intervening years I established ano maintained a system for collecting and digesting the rapidly growing technical literature on aflatoxins. This system, which is still intact, was soon expanded to all mycotoxins, and later to all natural toxicants. I was responsible for planning and interpreting the results of the aflatoxin or mycotoxin surveillance programs conducted by the FDA field offices since these programs were started in 1967. I was also responsible for the informal coordination of FDA research on aflatoxins and other mycotoxins with academia, industry, and other government agencies, a role that was facilitated by my appointment in 1970 as General Referee for Mycotoxins of the Association of Official Analytical Chemists.

The original FDA decision to control the level of aflatoxin in peanuts, and later in other foods, was a prudent action. It was based on the potency of aflatoxin as a liver carcinogen in laboratory rats, and, given the lack of knowledge at that time, the possibility that aflatoxin might also be a carcinogen for humans. The action level, that above which legal action against the contaminated commodity would be considered, was set at 20 ppb total aflatoxins. That was the minimum practical level at which the identity of the aflatoxin could be established with the analytical methods available in 1968. That level has no toxicological significance. Confirmation of the identity of the contaminant was needed for a legal case to be made.

As the FDA surveillance program on aflatoxin began to take hold, I started to look for a measure of the public health benefit that should accrue as a result of the reduction of the level of aflatoxin in human food, so that continuation of the program could be justified. I was surprised to find that in the United States liver cancer, the expected outcome of chronic exposure to aflatoxin, is a relatively rare malignancy. I also observed in the published results of the constantly increasing volume of research on aflatoxin that the strains of laboratory rats used in the original studies were peculiarly sensitive to aflatoxin carcinogenicity, and that

many species of animals were relatively resistant to its oncogenic effects. The differences were apparently related to the way each species metabolized aflatoxin. These observations were assembled in a paper published in 1976 (L. Stoloff and L. Friedman. Information bearing on the evaluation of the hazard to man from aflatoxin ingestion. PAG Bull. 6(2), 21-32, 1976).

In this same period, about 1975, the developing information on the metabolism of aflatoxin by animals, livestock in particular, indicated that aflatoxin was rapidly altered to excretable compounds, and that any residues in edible tissue would be but a very small fraction of the amount ingested by the animal. That information was presented at an international symposium on mycotoxins and published in the proceedings of that symposium (J.V. Rodricks & L. Stoloff. Aflatoxin residues from contaminated feed in edible tissues of food-producing animals. pp. 67-79 in Mycotoxins in Human and Animal Health; J.V. Rodricks, C.W. Hesseltine & M.A. Mehlman, eds., Pathotox Publ. Park Forest South, IL. 1977). The data has recently been updated and presented in a paper together with the rationale used by the FDA to justify the action guidelines for aflatoxin in animal fedstuffs (D.L. Park & A.E. Pohland. A rationale for the control of aflatoxin in animal feeds. pp. 473-482 in Mycotoxins and Phycotoxins; P.S. Steyn & R. Vleggaar, eds., Elsevier Science Publ., Amsterdam. 1986). That justification included information on the effects of aflatoxin on animal health.

Although liver cancer is a rare malignancy in the U.S., there are areas of Africa and Asia where the incidence of liver cancer is very high. To test the thesis that aflatoxin ingestion might be a factor in the occurrence of liver cancer in these areas, a number of epidemiological studies were conducted between 1970 and 1975 under various international auspices. The resulting data, taken together and at face value, provided a strong presumption that a relation existed between the level of aflatoxin ingestion and the incidence of liver cancer, but, a close examination of each of the published studies revealed serious flaws that cast a cloud over that conclusion. That conclusion was further weakened by the developing observations from all areas of the world that chronic infection with hepatitus B virus was closely associated with liver cancer. By 1980 the data was strong enough to consider chronic HBV infection the primary cause of at least 80% of liver cancers. Chronic HBV infection is endemic in the areas of

Africa and Asia where the aflatoxin/liver cancer studies had been conducted, confounding the results of these studies, which had not been controlled for that factor.

More important to the deliberations of this committee are the results of an epidemiological study of liver cancer in the United States (L. Stoloff, Aflatoxin as a cause of primary liver-cell cancer in the United States: A probability study. Nutr. Cancer 5, 165-186, 1983). This retrospective study has a much stronger data base than is found in all the studies of Asian and African populations and has no confounding problem with HBV infection. The populations compared are rural white males in the southeastern states with their counterparts in the north, central and western states. There was an approximately 1000 fold estimated difference in the past exposure of these populations to aflatoxin, with the highest exposures on a par with the highest in the Asian and African studies and of the same magnitude as the lowest level that produced a significant incidence of liver tumors in rats. In the face of this past exposure there is no significant difference in the lifetime risk of liver cancer between the test populations. In fact, the highest lifetime risk of liver cancer in the U.S. is in those populations most likely to be infected with HBV, Orientals and urban black males. Chinese males, the highest risk population in the U.S., have a 2.3% chance they will die of liver cancer, as high as any risk reported elsewhere.

You may be told that the International Agency for Research on Cancer (IARC) feels there is sufficient evidence to consider aflatoxin a probable human carcinogen. This was the conclusion of a Working Group convened in 1987. I have reviewed the evidence cited by IARC to support that conclusion. I found the evidence incomplete, some of the evidence incorrectly used, and other evidence employed without apparent critical examination, to the end that the conclusion was not supported by the evidence cited. From all the available evidence, critically examined, I do not see how one can objectively reach any other conclusion than it is highly unlikely aflatoxin is a human carcinogen.

However, there is good epidemiological evidence that aflatoxin is an acute hepatotoxin for humans, and should be regulated as such in foods.

Aflatoxin is also an acute toxin for livestock, and FDA action guidelines for aflatoxin in feed, as previously noted, take that information into account. Rationales for responsible regulation of aflatoxin have been published (L. Stoloff, A rationale for the control of aflatoxin in human foods. pp. 457-471 in Mycotoxins and Phycotoxins, P.S. Steyn & R. Vleggaar, eds.; Elsevier Sci. Publ., Amsterdam, 1986; D.L. Park & A.E. Pohland, A rationale for the control of aflatoxin in animal feeds. previously cited).

Leonard Stoloff
13208 Bellevue St., Silver Spring, MD 20904

Testimony prepared for delivery by Rodney E. Leonard, Executive Director of the Community Nutrition Institute before the House Subcommittee on Wheat, Soybeans and Feed Grains Subcommittee, Tuesday, April 4, 1989.

Mr. Chairman, members of the subcommittee:

I wish to thank the subcommittee for the opportunity to testify on the current problems related to aflatoxin contamination in the 1988 corn crop. The grain now is making its way through the nation's food system, and will continue to do so for the next two to three years.

The Community Nutrition Institute is a non-profit organization that has sought over the past 20 years to represent a consumer viewpoint in food policy issues, including food safety. We are located in Washington, D.C. We publish Nutrition Week, the leading weekly publication on food and nutrition issues, with a readership of about 20,000.

We also provide research support to members of Congress and their committees and staff, and we raise public policy questions on issues relating to food, nutrition, health and hunger. We provide information to the public, including the media.

We address policy issues by publishing reports and studies, by testifying before Congress and State legislatures and through legal action related to Federal rules and regulations.

Over the past 10 years, for example, we have been locked in a legal struggle with the Food and Drug Administration (FDA) over aflatoxin, and it is from this perspective that I am submitting this testimony. Our objective was and is straightforward. FDA has failed to regulate aflatoxin as an unavoidable contaminant under the Food Drug and Cosmetic Act. This failure threatens the public health and, as I will outline, endangers the economic health of American farmers. We believe the American people deserve better protection of their health and safety than FDA is willing to provide, and that the agricultural economy should not be put at risk.

In the late 1970s FDA said it intended to begin steps to reduce the overall level of aflatoxin contamination in grain, peanuts and other food or feed crops grown in the U.S. Aflatoxin is one of the most carcinogenic substance ever tested. The agency said its concern was based on a National Academy of Science report which came to the same conclusion. The report urged the Federal government to do more to protect the public. The World Health Organization (WHO) also regards aflatoxin as a major health threat. WHO studies show aflatoxin is the primary cause of liver

cancer in Africa and the Middle East, where the disease is more prevalent than in the U.S., and is a major killer. Large scale losses of turkey and broiler flocks in the U.S. and Europe at the time were traced to aflatoxin contamination in U.S. grain. The substance also is linked with mental retardation in U.S. epidemiological studies.

We applauded FDA's intentions, but then discovered its concern about the health of the American people was not reflected in agency practices. Although FDA said the level of aflatoxin should not exceed 20 parts per billion in grain shipped in interstate commerce, the agency routinely authorized State governments to disregard the FDA standards.

Those authorizations were done privately, by letter, without any notice to the public that FDA was doing in private what it was saying publicly should not be done. Grain at levels exceeding 20 parts per billion was allowed to be shipped across state lines, and contaminated grain was mixed with clean grain, compounding the contamination. Those private agreements had all the force and intent of a rule; they sheltered the grain and the food industries from enforcement of Federal law. No one, not even the consumer at risk, could comment on or question the decision, however. We felt this was, and is wrong, and asked the Federal courts to correct the situation.

Aflatoxin contamination occurs regularly, at least two to three times a decade. Aflatoxin was a problem in the early 1970s, again in the latter years of the 70s, and again in 1980 when FDA said it would allow corn to be used for livestock feed if the level of aflatoxin did not exceed 100 parts per billion. We asked the Federal courts in 1980 to order FDA to establish tolerances for aflatoxin. We wanted the agency to publicly disclose the data it was using to make these decisions. We also asked the court to require FDA to give public notice and to obtain comments prior to any regulatory action, as Federal law requires.

The issue was before the Federal courts for almost seven years, going all the way to the Supreme Court. Two more outbreaks occurred during this time, including the 1988 outbreak. FDA never challenged the assertion that aflatoxin is a dangerous carcinogen. The Supreme Court found the substance to be "a potent carcinogen." The U.S. Circuit Court of Appeals found that the Food, Drug and Cosmetic Act was clear in its language that "(FDA) shall promulgate regulations limiting the quantity (of unavoidable contaminants) to such extent he finds necessary to protect public health." The Supreme Court, however, found the language ambiguous and said FDA was not required to promulgate tolerances, and returned the question on public notice to the lower court.

The Circuit Court found that FDA, in its handling of aflatoxin standards, had been developing rules that had the force and effect of law. Public notice was required.

FDA, however, found a loophole through which it could slip. Last September when the current aflatoxin outbreak was discovered, FDA issued what it called guidelines. The agency said the guidelines might be used in determining if a company or individual were in violation of the FD&C Act — if FDA decided to enforce the Act, which it might or might not do.

Those guidelines raised the allowable level of aflatoxin to 300 ppb in corn used to feed cattle, with lower levels set for hogs and poultry. The limit for corn fed to dairy cows was set at 20 ppb, and milk for human consumption could not exceed aflatoxin levels of 0.5. Corn used to make food products could not contain more than 20 ppb.

FDA pointedly declined to ask for public comment since the guidelines are not considered by the agency to shield users from enforcement action. The agency continues to shield itself from public scrutiny by withholding the data on which the standards are based. The public cannot evaluate whether the research is adequate to support FDA's position, or that the risks to health are greater than FDA should permit. We have FDA's word that the public health is being protected, but we also had assurances that imported fruits and vegetables are safe, and that Alar and other chemicals do not pose a health threat. The injury caused by aflatoxin today will not become visible as a cancer until 20 years have passed, and FDA will not be associated with any rise in liver cancers a generation hence.

In essence, FDA's policy toward regulation of aflatoxin is unchanged. The agency does not have an enforcement mechanism, does not want an enforcement mechanism and will not develop an enforcement policy. Rather, the rules will be changed to facilitate the shipment and use of aflatoxin contaminated grain. The reliance on guidelines is an admission that no legal steps to control aflatoxin will be taken because the agency has no legal standards to protect, nor does it have any system to detect threats before they become risks to public health. Any legal action would be a symbolic gesture, at best A court decision penalizing one violator poses no threat to other violations since FDA must take each violator to court and prove in every case that the law has been violated. Given the length of time involved in such litigation, the threat to health will long have passed before a decision is reached, and the harm that should be avoided will have been done. FDA does not have — nor does it need— the resources to clean up the situation on a case by case basis.

The situation conjures up an image of FDA as the host of the Mad Hatter's party, with the refreshments laced with aflatoxin. In that context, any outbreak of aflatoxin, by definition, cannot be a health problem, because FDA says no threat exists. And, anyone who argues to the contrary — as for example, the Wall Street Journal — is immediately sentenced to lose their heads.

Our seven-year legal battle on aflatoxin provides a number of conclusions and offers some opportunities for new directions. For example:

1. Regulatory agencies will do as they please unless the laws on safety and health are written so as to preclude all other options than the explicit course desired by the Congress;

2. The law on and regulation of unavoidable contaminants almost dictates a passive approach to health protection, which means that legal steps to protect health and safety are too late once an outbreak occurs;

3. Aflatoxin outbreaks occur regularly, at least two to three times each decade in the U.S.;

4. FDA does not want to reveal the risk assumptions it is using in setting the present standards for aflatoxin in foods and in animal feed. In the case of milk where the FDA allows up to 0.5 ppb, other countries, including the European Community, have set a maximum 0.05 ppb. The EC, for example, is considering steps to bring the maximum level down even further, primarily because the 0.05 ppb level assumes a maximum risk of 50 additional cancer deaths per million population over a lifetime. This suggests the level of exposure at 0.5 ppb corresponds to a 500 in one million lifetime cancer deaths. For some perspective, FDA and the Environmental Protection Agency use one additional death per million as a benchmark in evaluating allowable levels of chemicals and pesticides in food. We have asked FDA to state publicly the lifetime risk of cancer that consumers can expect at the action level in milk of 0.5 ppb contained in the October 4, 1988 guideline memo to its regional offices.

5. Other countries, particularly those that import grain, are rapidly developing tolerance levels for aflatoxin in animal feed and in foods. The EC, for example, has lowered the allowable level of aflatoxin in feed for milk cows to 10 ppb, half of the current U.S. standard, and has established 200 ppb for beef cattle (compared to 300 ppb in the U.S.). Where 22 countries had standards for animal feed in 1981, the number had increased to 35 in 1986, according to a recent World Health Organization (WHO) study. Some 50 countries have aflatoxin regulations for foods, and of those, 14 had tolerances specifically for milk.

Those numbers can be expected to increase, and the tolerance levels will start to come down, particularly as consumers begin to understand the substantial risk to health that is involved. This pattern has a number of implications, but the most important for U.S. agriculture and the current policy to promote exports is that importers will not buy U.S. grain if it is contaminated by aflatoxin. The world grain market is growing increasingly competitive, and aflatoxin is rapidly becoming a standard of quality. The country that offers clean grain free of aflatoxin will be the most successful in dominating world trade.

We already have seen that pattern develop in relation to the 1988 corn crop, with the EC, the Soviet Union and Japan imposing aflatoxin tolerances on U.S. grain that are much tighter than those FDA permits for use in the U.S. American consumers will not accept second best for very long.

**Recommendations:**

The regulatory strategy for aflatoxin, and for other similar threats to human health from mycotoxins, should focus on prevention, and should incorporate the following activities:

a. Harvesting techniques and technologies should be evaluated for their effect on aflatoxin contamination, and those which tend to promote or encourage mold growth should be modified or replaced. Incentives for producing clean grain should be built into the price support program for grain;

b. A method to detoxify, or neutralize, aflatoxin should be developed and tested by the Federal government, with ongoing research to monitor the effectiveness of current methods and to develop more efficient procedures and systems;

c. A network of testing facilities should be developed jointly by Federal and State governments to assure quick turnaround on tests; and, testing facilities should be monitored for reliability of testing procedures;

d. Aflatoxin standards for milk should be lowered to 0.01 ppb, and testing for aflatoxin should be required for raw milk. A five year timetable should be developed to do this;

e. Mixing of clean grain with aflatoxin contaminated grain should be prohibited; and, a procedure should be developed and put in place over the next five years to collect and isolate grain with high levels of aflatoxin;

f. The standard applied to aflatoxin at the Federal level should also become the same standard in each State:

g. The standards for aflatoxin in foods and feedstuff should be lowered regularly over a five year period.

(Attachment follows:)

Community
Nutrition Institute

2001 S Street, N.W., Suite 530 Washington, D.C. 20009 (202)462-4700

April 3, 1989

Frank E. Young, M.D.
Commissioner
Food and Drug Administration
200 "C" Street S.W.
Washington, D.C., 20204

Dear Dr. Young:

Following the issuance October 4, 1988, of a memo outlining a policy on aflatoxin to guide the regional offices of FDA, we had expected your agency to publish in the Federal Register the basis for the levels of aflatoxin cited in the memo and to provide an assessment of the cancer risks assumed in those levels. No such information has been published, however.

We understand that FDA uses a published linear interpolation process to calculate the maximum risk of cancer from tumor incidence data obtained from rodent feeding studies. We also understand that Professor Dennis P. Hsieh and colleagues at the University of California, Davis, last year published results of a carcinogenicity study of aflatoxin M(1) in rats. Using this study, we ask that you provide a maximum lifetime risk of cancer that will be experienced from aflatoxin M(1) at the agency action level of 0.5 parts per billion for aflatoxin in milk.

We realize the study suffers from shortcomings as a basis for cancer risk assessment, but we also understand this is not an unusual condition faced by risk assessors.

We ask that you conduct the best possible risk assessment and accompany it with any qualifying remarks you deem appropriate. Would you also inform us of any assumption you use, such as the amount of milk ingested each day and the differences in exposure levels that should be applied for adults as compared to children.

Thank you for your assistance.

Sincerely,

Rodney E. Leonard

Rodney E. Leonard
Executive Director

## National Grain and Feed Association

**Testimony of the**
**National Grain and Feed Association**

**Before the**

**Subcommittee on Wheat, Soybeans and Feed Grains**

**House Agriculture Committee**

**on**

# Safeguards in the Grain and Feed Industry Pursuant to Aflatoxin

**April 4, 1989**

Thank you, Mr. Chairman and members of the Subcommittee. I am Lyle S. Kuhlmann, president of the Byron Elevator Company in Byron, Minnesota. I am Chairman of the National Grain and Feed Association's Feed Industry Committee, and immediate past chairman of its Country Elevator Committee. Appearing with me is James Rutledge, vice president of food protection services for the Lauhoff Grain Company, Danville, Illinois. We are accompanied by Randall C. Gordon, vice president, communications and government relations for the NGFA. It is on behalf of the 1,350-member companies of the NGFA representing country elevators and feed mills, terminal elevators, grain processors and exporters that we testify today.

We welcome this opportunity to share with the Congress the kinds of safeguards and checkpoints that exist in the grain and feed marketing and distribution system to ensure

American consumers and our export customers are furnished with a wholesome and safe food and feed supply.

At the outset, I think it is important to make two observations. First, our industry considers aflatoxin to be a serious matter, and places a great deal of emphasis on detecting and keeping it out of the food and feed supply. Second, aflatoxin, a naturally occurring substance, is not a perennial or pervasive problem. Its occurrence, particularly in the major corn-growing states, is confined to years in which extreme weather conditions exist. That is what occurred in 1988. Yet even with the worst drought in half a century, the incidence of aflatoxin was confined mostly to isolated areas of Iowa and Illinois. Little to no aflatoxin was detected in such major corn-producing states as Minnesota, Nebraska and Ohio.

While its occurrence fortunately is the exception and not the rule, the grain and feed industry has coexisted with aflatoxin for years and is well aware of the concern it raises. Our industry reacts quite dramatically when weather conditions appear to indicate that it may emerge in the growing crop.

The National Grain and Feed Association has been extremely active in working with the Food and Drug Administration, the Federal Grain Inspection Service and other affected governmental agencies in those sporadic years when aflatoxin emerges. In 1983, which until the 1988 experience was the most recent year in which aflatoxin emerged in some of the main corn-growing regions, the NGFA initiated a series of educational workshops between FDA and key members of the industry to share information on geographical areas where aflatoxin appeared to be a problem, and recommended procedures to screen and detect for its presence. Those workshops also spurred a review by FDA of its regulatory procedures concerning aflatoxin, and fostered a better understanding among the agency and the industry on how those procedures operate.

This sharing of information on crop conditions and regulatory procedures with FDA has continued to this day, and greatly facilitated the communication of FDA's regulatory policies concerning the 1988 crop to the industry.

The widespread dissemination of information on aflatoxin in the 1988 crop was spear-headed not only by the NGFA, but by its Affiliated State and Regional Grain and Feed Associations serving areas where aflatoxin emerged or was suspected. Through trade association newsletters, publications, seminars and workshops, an intense effort was made prior to and during last year's harvest to inform the industry about the occurrence of aflatoxin and available techniques and procedures for screening shipments for its presence. That effort was assisted greatly by the trade and farm press. I would like to submit to the record a sample of the kind of information on aflatoxin that was published during the 1988 crop year.

The point I wish to make is that the dissemination of information concerning aflatoxin during years in which it is a problem has developed to a degree that it is virtually impossible not to be aware of it.

In years when the incidence of aflatoxin is suspected, the multi-layered protections to which I referred earlier start long before harvest. Those protections begin where the corn originates -- that is, at the producer and country elevator level.

In areas where aflatoxin is suspected, producers and country elevators actually begin working together to identify and quantify the extent of the problem while the corn crop still is on the stalk. University agronomists and grain scientists in affected areas also conduct widespread sampling of the growing crop, as do state regulatory agencies. Educational meetings for producers and grain elevator operators are conducted to provide guidance on how to detect aflatoxin; proper harvesting, drying and storage procedures; and ways to sample and screen for the presence of aflatoxin in incoming shipments at the elevator.

In a year like 1988, when extreme weather conditions existed that signaled the potential emergence of aflatoxin, it is commonplace for country elevators to perform screening tests on incoming shipments to detect whether aflatoxin is present, particularly in areas where pre-harvest surveys indicate the crop may be susceptible. An informal survey conducted by the NGFA of manufacturers of four of the more popular quick aflatoxin-detection tests found that more than 400,000 such tests were sold during the 1988 harvest. It is important to note that this does not account for the extensive use of black-light screening procedures that have become routine at elevators in affected regions.

There are several powerful economic incentives for elevators to do what they can to avoid handling corn containing aflatoxin that cannot be directed to FDA-approved uses. Country or terminal elevators that take delivery and commingle corn containing aflatoxin at levels above legal limits risk having the contents of their entire elevator seized and condemned by state and federal officials if they subsequently ship corn containing violative aflatoxin levels. Further, grain company contracts typically contain clauses that require grain sold to be compatible with FDA regulations; shipments not meeting those standards are deemed to be "unmerchantable," and are rejected by receivers at considerable expense to the shipping elevator. That's especially true if the destination is in a market area for which no approved use for the corn exists.

Once the incoming shipments are stored, proper grain drying, aeration and conditioning are used to minimize, if not eliminate, the possibility of mold growth developing which would result in an aflatoxin residue.

Perhaps I can best illustrate these procedures by briefly sharing with you how the state of Minnesota and my own firm responded to the reported incidence of aflatoxin in the 1988 crop. When it became clear the drought could make the crop susceptible to aflatoxin in some states,

our two state associations -- the Farmers Elevator Association of Minnesota and Northwest Agri-Dealers Association Inc. -- joined forces with University of Minnesota Extension aflatoxin specialists to conduct three workshops. Those workshops, attended by about 250 elevator managers and operators, provided education on proper sampling, testing and safety procedures. A fourth such seminar attracting about 150 elevator managers was conducted by the Southeastern Grain and Feed Dealers Association of Minnesota. In all, the University of Minnesota conducted 12 such seminars with industry and producer groups. Separate meetings were conducted with vo-ag instructors and county Extension agents.

The Minnesota Department of Agriculture collected more than 2,000 random samples of grain, seed and grain byproducts to check whether aflatoxin was present. Of those samples, the state reports that only 13 contained more than 20 parts per billion, the action level at which FDA controls begin.

At my elevator and feed mill in Byron, Minnesota, we worked with our producer-customers to examine the 1988 crop prior to harvest. We performed field tests with farmers in suspect areas. Even though we did not find any incidence of aflatoxin in the growing crop in our immediate market area, our company adopted a policy of using only 1987-crop corn in our local shipments and feed mill rations for one month after harvest began until we were assurred that the new-crop corn we were receiving was safe. Incoming grain from the farm was blacklighted, a technique university researchers informed us provides relatively accurate determinations of aflatoxin at levels exceeding 20 p.p.b. Any suspect samples were tested with quick-cards; no samples were found to contain aflatoxin. Despite this, we screened all incoming corn to remove broken kernels and foreign material prior to storage, since we had been advised by the University of Minnesota and larger terminal elevators that broken kernels and foreign material are more susceptible to aflatoxin than whole kernels. The same procedure was followed on outbound shipments. As an aside, I should note that there is a strong economic incentive to do this, as well, since the market discounts for corn containing

more than the allowable amount of foreign material are extremely steep. Corn screenings were diverted to a large cattle feeder nearby for use in mature beef cattle. We ensured the quality of our livestock feed by closely monitoring the corn used to manufacture the rations.

Similar procedures were implemented at other elevators and feed mills in Minnesota, as well as in states where early field tests indicated aflatoxin might be a problem.

Let me now turn to Mr. Rutledge to explain the kinds of procedures used in the dry corn milling industry to safeguard breakfast cereals, mixes, snacks and other consumer products:

(Testimony by Mr. Rutledge.)

As Mr. Rutledge has explained, processors and food companies have extensive quality control programs in place utilizing sophisticated laboratory tests to detect the presence of aflatoxin in incoming shipments from country elevators long before products ever reach the consumer.

Likewise, terminal elevators and exporters routinely test incoming and outbound shipments for the presence of aflatoxin. The reasons are simple: First, most export grain contracts specify that corn shipments contain 20 p.p.b. or less, the level considered safe for human consumption. Second, grain containing higher levels of aflatoxin may not be applicable to the export sale if it does not meet the standards of the importing country. In addition, foreign buyers can -- and most in fact do -- require aflatoxin testing as a condition in the export contract itself. These tests are performed by FGIS utilizing the most sophisticated laboratory techniques available. It is NGFA's understanding FGIS has not received a single confirmed report of shipments of corn during the 1988-89 marketing year that contained violative levels of aflatoxin.

It bears emphasizing that the protections and safeguards in place at export elevators exist for the same reason they do at the producer, country elevator, terminal elevator, feed mill, processor or food manufacturer. In the highly competitive marketplace in which our industry operates, a company can ill afford to have its reputation or integrity undermined by reports that it handles or ships corn or corn products that contain illegal levels of aflatoxin.

At the producer level, Congress recognized the financial harm that a farmer could experience because of aflatoxin when it enacted the Disaster Assistance Act of 1988. Producers who sustained crop losses sufficient to qualify for disaster payments also are eligible to receive disaster payments on corn containing levels of aflatoxin that exceed 20 p.p.b. In effect, such corn is considered to be "lost production." Further, producers are obligated to deliver corn containing less than 20 p.p.b. as collateral for federal price support programs. Warehouses storing Commodity Credit Corporation-owned corn are similarly obligated to deliver corn that does not exceed 20 p.p.b.

Our discussion of the safeguards and protections that exist at various stages of the grain marketing and distribution system -- from the farmer to the ultimate consumer -- is not to say that improvements cannot be made. Indeed, FGIS is in the midst of a project designed to meet perhaps the most pressing need: a study that is evaluating the performance, accuracy and reliability of quick aflatoxin-detection tests being marketed by several different manufacturers. Fortunately, the free enterprise system has fostered development in the last several years of new, quick and relatively inexpensive chemical-based tests that can be used by producers and country elevators to check for the presence of aflatoxin at the first step in the food chain. These tests are receiving increased use in our industry, and will complement the use of the blacklight as a screening method. We commend FGIS for initiating this study and hope it can be completed as expeditiously as possible. For grain elevator operators and producers -- and indeed for our customers -- it is vital that any test yield results that are as accurate and repeatable as possible in a working environment.

Combined with the increased understanding of the environmental conditions that foster mold growth resulting in aflatoxin residues and the development of seed varieties more resistent to mold invasion, the results of this FGIS study has the potential to further improve the already considerable ability of producers and the grain, feed and food industry to safeguard our nation's food and feed supply.

Mr. Chairman and members of the Subcommittee, we appreciate your time and interest, and would be pleased to respond to any questions you may have.

## National Grain and Feed Association

### Testimony of the National Grain and Feed Association

### Before the

### Subcommittee on Wheat, Soybeans and Feed Grains

### House Agriculture Committee

### on

### Safeguards in the Grain and Feed Industry Pursuant to Aflatoxin

### April 4, 1989

Mr. Chairman, members of the Subcommittee, I appreciate the opportunity to appear before you to address the important subject of aflatoxins in corn and corn products. My name is James Rutledge. I am Vice President of Food Protection Services for Lauhoff Grain Company.

Lauhoff Grain Company is a large dry-corn milling firm with plants located in east central Illinois and southeastern Nebraska. We supply milled corn products which are used as ingredients in the manufacture of a variety of human foods such as breakfast cereals, corn-based snack foods and beer. Our customers have strict standards of quality concerning the safety of ingredients they purchase. Similarly, we have very strict standards of quality concerning the safety of the ingredients we sell.

My purpose in appearing before this subcommittee is to give assurance that the industry is very much aware of the potential hazard of aflatoxins in corn, and that active measures are being taken to guard against levels of aflatoxins in food that could pose a risk to public health. I must speak primarily from the standpoint of what we do at Lauhoff Grain Company. We began monitoring corn and corn products for aflatoxins back in 1971 and we have continued to do so since that time.

The raw material for our milling operations is shelled corn which is delivered to our plants primarily by trucks from a series of country grain elevators. Every inbound shipment of raw corn is sampled and inspected prior to acceptance into our facilities. Using large, mechanized probes, we take a series of individual samples which make up a composite sample from each truck load. Those composite samples are individually examined under ultra-violet light to detect the typical flourescence associated with the presence of aflatoxins. Suspect samples are further analyzed in our laboratories using a test procedure approved by the Association of Official Analytical Chemists, and the corn shipments from which the samples were drawn are only accepted if the samples from them test negative for aflatoxins. To back up our program of rigid examination of inbound corn, we continuously take samples of our finished corn products and test them in our laboratories for aflatoxins. That testing verifies the effectiveness of our raw corn inspection program. If any of our food products did test positive for aflatoxins in our laboratories, we would redirect those products to a non-food use. Further, we routinely forward product samples to an independent testing laboratory to substantiate our own analytical data.

It may also interest the subcomittee to know that we produce corn-based products that are sold to the United States Government for distribution through the P.L. 480 Food for Peace Program. Those products fall under the inspectional jurisdiction of the U.S. Department of Agriculture, Federal Grain Inspection Service (FGIS). We have been advised that the FGIS

laboratory analyzes each shipment for aflatoxins. To the best of our knowledge, there have not been any positive aflatoxin test results reported for shipments of our products. That represents hundreds of tests by the FGIS laboratory, which further illustrates the effectiveness of our afltoxin control efforts.

I hope the statement just given has elevated the degree of confidence the subcommittee has in the efforts being taken to control the potential hazard of aflatoxins in food.

STATEMENT OF KYD D. BRENNER
CORN REFINERS ASSOCIATION, INC.
SUBCOMMITTEE ON WHEAT AND FEED GRAINS
HOUSE COMMITTEE ON AGRICULTURE
APRIL 4, 1989

Mr. Chairman and members of the subcommittee: I am Kyd Brenner, director of public affairs of the Corn Refiners Association, Inc. The Corn Refiners Association is the national trade association representing the corn wet milling industry - producers of corn sweeteners, corn starches, corn oil, feed ingredients and fuel alcohol. A list of members of the Association is attached. Since 1975 I have worked with technical committees of the wet milling industry, affiliated associations and users of corn wet milling products on questions invclving the occurrence of aflatoxin in corn.

We appreciate the opportunity to appear here today to outline the measures which have been taken by the corn refining industry to assure the safety of the corn-based food ingredients which Americans have come to rely on.

Corn refining is the second largest domestic use for corn, and refiners now buy about 15 percent of an average year's corn crop. About 550 million bushels of corn are purchased for processing into sweeteners, 150 million bushels are processed for corn starch and 200 million bushels are refined into fuel-grade ethanol. An important co-product of this process is over one billion pounds of refined corn oil. As major suppliers of food ingredients for literally hundreds of grocery products, corn

refiners are committed to taking every precaution to prevent aflatoxin from finding its way into America's food supply.

We must first recognize that the presence of aflatoxin in raw agricultural commodities is not new. The problem of natural contaminants such as aflatoxin has been with us since man first harvested crops. It is not a problem that we can hope to legislate or regulate out of existence, any more than we can hope to legislate the weather which contributes to its occurrence. However, we can hope to devise effective strategies to identify and control its effects on the food system.

Although an old problem, our knowledge of aflatoxin is relatively new. Aflatoxin was first recognized as an animal toxin in 1960 after the death of turkey flocks in England which were fed highly contaminated peanut or groundnut meal. Aflatoxins have been identified as occurring in a wide variety of commodities, including peanuts, cottonseed, rice, sweet potato, various beans, wheat products and even wine.

Beginning in the early 1960s, the peanut industry, in conjunction with the Food and Drug Administration, undertook an extensive research and control program to prevent contamination of food products with aflatoxin. Because of close corporate ties between a number of peanut processors and corn wet millers, the corn refining industry was able to observe closely the development of these programs, and begin adapting them to the needs of the corn industry. In 1965 the industry conducted the first of a number of crop and product surveys designed to

determine the incidence of aflatoxin in corn delivered to processing plants and the incidence of aflatoxin in corn products. Concurrently, laboratory personnel in the industry worked extensively with the USDA and FDA on development of effective detection methods.

In 1966, the first study of food products from the industry was published demonstrating that refined vegetable oils processed from deliberately-spiked raw materials did not contain aflatoxin.

In 1971, results of a five-year program to determine the possibility of aflatoxin contamination of corn starch and its products were published. Food products of corn wet millers such as corn syrups, high fructose corn syrups and food-grade starch are derived from the starch portion of corn. This program analyzed both naturally contaminated corn and corn which had been deliberately spiked with extremely high levels of aflatoxin. In all cases, corn starch after the wet milling process was found to be essentially free of aflatoxin.

In 1974, the Corn Refiners Association again sponsored an extensive survey of both corn and corn products under the direction of the Wisconsin Agricultural Research Foundation. As in earlier surveys, no contamination of food ingredients with aflatoxin was detected.

Despite the assurance from this work that corn starches, sweeteners and oil are aflatoxin-free, the corn milling industry has remained alert to the possibility of receiving aflatoxin-containing corn, and members have developed action plans to avoid

purchasing corn which does not meet the FDA action level of 20 parts per billion.

Aflatoxin is generally found in corn which has been subject to particular weather patterns which cause dryness and breakage of corn kernels in the field and later invasion of the kernel by mold. These same conditions produce corn which is more difficult and costly to process. Therefore, refiners begin their aflatoxin control programs well before harvest by monitoring weather conditions and crop development in areas where corn is usually purchased. Based on this information millers can project prior to harvest if any of their normal corn purchasing areas may have potential aflatoxin problems. Certain regions of the country, primarily in the southeast, have been repeatedly shown to have these conditions, and the corn refining industry does not purchase corn from these areas.

After this initial assessment of crop conditions, refiners can determine the extent of incoming corn testing which may be appropriate. In years of good growing conditions a statistical sampling plan will determine the extent of testing of incoming corn. In all years, the frequency of testing is increased as new-crop corn begins to enter the marketing chain. Through this program, any areas which are exhibiting unusual conditions can be identified and eliminated from the incoming corn supply. This type of testing is called for even in years with good crop quality, since aflatoxin is often found in very small, localized areas, but not in a significant portion of the overall corn

supply. Such a case occurred in 1975 when several counties in western Iowa had a higher than normal aflatoxin incidence while the crop in general was aflatoxin-free. Similar conditions occurred in the southeast and limited areas of the corn belt in 1983.

Nineteen eighty-eight was the first year since the discovery of aflatoxin in which conditions have been conducive for aflatoxin development in more than a very limited portion of the corn belt. Because these conditions were well known before harvest, corn refiners were prepared when new crop corn began to move in marketing channels. Testing of incoming corn was increased to cover all incoming corn. The level of sampling and testing of in-process and finished corn products was greatly increased, and plans were developed for handling the commercial operations of rejecting corn containing unacceptable levels of aflatoxin.

Three levels of testing incoming corn are used by corn refiners. A screening test, using either black-light or immunoassay test cards, is conducted on all incoming grain. Depending on the location and the basis on which the grain has been purchased, a positive result on this screening test triggers either rejection of the grain or a further series of tests. If further testing is called for, either a minicolumn or chromatographic test is conducted. The minicolumn method will indicate if the corn is above or below a particular aflatoxin content and serve as the basis for an accept/reject decision.

If, for contractual reasons, it is necessary to determine the precise aflatoxin content of a disputed shipment, either thin-layer chromatography or liquid chromatography methods are employed.

Once corn has been accepted and placed into the wet milling process, samples of various process streams are drawn and tested for aflatoxin. These in-process analyses serve as a double check on the incoming corn testing and an assurance that corn sampling has been adequately conducted.

This program resulted in rejection of a substantial quantity of corn by the wet milling industry in the early months of the new crop. It appears that corn which was in the worst condition in fields was harvested first, and this apparently accounts for the higher level of aflatoxin found in September of 1988. Since that time, the rate of rejection by corn wet millers has steadily declined. It appears that the general quality of the crop coming to market is better, and the grain industry has made a concerted effort to be sure that corn which is shipped to the food industry is aflatoxin-free.

Beyond the efforts made by corn refiners, a wide variety of systems are in effect to keep aflatoxin in the food system at a minimum.

First, despite erroneous press reports, the Food and Drug Administration is very active in surveillance of the food industry for aflatoxin. FDA inspectors have been in many corn refining plants since last fall, sampling grain and corn products

and inspecting the quality control programs of individual processors. In addition, the changes made in FDA action levels last fall have provided an outlet in feed for grain which is above 20 ppb aflatoxin, eliminating the incentive for farmers or grain merchants to send contaminated corn to the food industry. The approval of blending, under FDA supervision, has also relieved pressure to try and move contaminated corn.

The grain industry has been very responsive to the needs of food processors for corn which meets FDA guidelines for human food. Not only have the new FDA guidelines for feed corn provided an approved market for corn over 20 ppb, the grain industry is well aware that refiners are testing all corn and are not hesitant to reject suspected lots.

Finally, USDA programs to permit farmers to include contaminated corn in disaster relief programs designed to deal with last year's drought have helped to remove the incentive for individual farmers to pass contaminated grain further up the marketing chain.

Taken together, the efforts of the FDA, USDA, the grain industry and the corn refining industry are extensive, systematic and more than adequate to insure the integrity of the food ingredients from corn wet milling.

One of the reasons we are here today is because of the publication of an alarmist article concerning aflatoxin in the Wall Street Journal in late February. A copy of a letter to the Journal from CRA President Robert C. Liebenow is attached to our

testimony. Without dissecting each inaccuracy of the article, I would like to note that it entirely disregarded the sincere, time consuming and expensive efforts of many individuals in the corn industry, the USDA and the FDA to control a highly unusual situation. In the process, this article also contributed to a totally unwarranted climate of hysteria concerning the safety of common foods.

Since tne discovery of aflatoxin, scientists in government, academia and industry have been involved in continuous development of better methods of detection and control for this unavoidable and naturally-occurring contaminant. This process continues today. The recent development of immunoassay test kits for aflatoxin holds great promise, and we look forward to the results of the current FGIS evaluation of these kits. Such a method has just been recommended for official use with cottonseed products and mixed feeds, and new studies could prove its acceptability for whole corn as well. In addition, other rapid methods are on the horizon.

Beyond development of better and quicker tests, there are a number of steps which can be taken to continue to minimize the effect of aflatoxin on the food system:

1. Continue and intensify the programs of education at all levels of crop production and marketing concerning screening for aflatoxin, and harvesting, handling and storage conditions which can minimize its occurrence.

2. Continue breeding research into drought-resistant strains of corn which could also be resistant to invasion by the aspergillus flavus mold.
3. Continue research into potential methods of destruction of aflatoxin which would be both effective and safe.
4. Finally, and most important, recognize that aflatoxin remains an occasional and limited concern, and avoid precipitous actions which would cause the public to lose confidence in a safe and abundant supply of corn.

Thank you very much for your time and attention. I will be pleased to answer any questions you may have.

# # #

(Attachments follow:)

MEMBER COMPANIES
Corn Refiners Association, Inc.
1100 Connecticut Avenue, N. W.
Washington, D. C. 20036

ADM Corn Sweeteners
(A division of Archer Daniels
Midland Company)
P. O. Box 1470
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Plants:
Cedar Rapids, Iowa
Decatur, Illinois
Clinton, Iowa
Montezuma, New York

American Maize-Products Company
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Plants:
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Decatur, Alabama
Dimmitt, Texas

Cargill, Incorporated
P. O. Box 9300
Minneapolis, Minnesota 55440

Plants:
Cedar Rapids, Iowa
Eddyville, Iowa
Dayton, Ohio
Memphis, Tennessee

CPC International Inc.
International Plaza
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Plants:
Argo, Illinois
Stockton, California
Winston-Salem, North Carolina

National Starch and Chemical
Corporation
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Bridgewater, New Jersey 08807

Plants:
Indianapolis, Indiana
North Kansas City, Missouri

Penford Products Co.
(A division of PENWEST, LTD.)
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Cedar Rapids, Iowa 52406

Plant:
Cedar Rapids, Iowa

A. E. Staley Manufacturing Company
P.O. Box 151
Decatur, Illinois 62525

Plants:
Decatur, Illinois
Morrisville, Pennsylvania
Lafayette, Indiana (2)
Loudon, Tennessee

THE WALL STREET JOURNAL - MONDAY - MARCH 20, 1989

## Letters to the Editor

# *Corn Industry Stalks the Fungus*

The Feb. 23 page-one article on aflatoxin ("Fungus in Corn Crop, a Potent Carcinogen, Invades Food Supplies") suggests the food industry is not taking proper steps to preserve a safe food supply.

Regarding the charge, without attribution, that one-third of the official corn samples in Iowa and Illinois had "dangerous levels of aflatoxin": Official samples are not selected randomly and are not representative of the corn crop as a whole. They are disproportionately made up of corn already suspected of containing aflatoxin as a result of initial screening. In fact, 80% of randomly sampled corn in areas susceptible to aflatoxin met the Food and Drug Administration standard as safe for humans.

Regarding the suggestion there is "widespread ignorance and disregard" for aflatoxin hazards: This may be true among the general public, but the most cursory review of farm and food trade journals and press sources will show a high level of aflatoxin awareness. Thirty years ago, our industry pioneered in developing methods to detect aflatoxin problems, and we continue to refine those methods today.

Regarding the suggestion that aflatoxin "is finding its way into" food products and processed foods: Food companies typically have even stricter limits on aflatoxin in raw materials than what the FDA requires. More than 20 years ago, the respected technical journal Cereal Chemistry published research showing that the corn-refining process prevents mycotoxins such as aflatoxin from entering the industry's food products. But even with that assurance, corn refiners monitor the corn crop to be alert to any aflatoxin occurrences. They test every truck or carload of grain that comes into the plant. They test their finished corn products as a final step in quality control.

It's unfortunate that many readers won't make it to the end of the article, where you discuss Quaker Oats' quality-control efforts, because the Quaker Oats program, like the corn refiners' program, is representative of the efforts being made by the food-processing industry to prevent aflatoxin problems.

ROBERT C. LIEBENOW
President
Corn Refiners Association
Washington

Corn Refiners Association, Inc.

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Executive Offices

April 5, 1989

Hon. Dan Glickman
Chairman
Subcommittee on Wheat, Soybeans
and Feed Grains
Committee on Agriculture
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

We would like to take this opportunity to further clarify concerns which were expressed at yesterday's hearing concerning the possibility of blending of aflatoxin-contaminated corn with aflatoxin-free corn.

Members of the Corn Refiners Association, Inc. do not, will not and may not engage in this practice. Press reports from yesterday's hearing indicate a perception that blending is an acceptable procedure, both from a business standpoint and under the law. Neither is the case.

The Food and Drug Administration has a longstanding enforcement policy prohibiting the blending of adulterated food with non-adulterated food to meet either food safety or aesthetic standards. Corn containing over 20 ppb aflatoxin is, with limited exception, considered adulterated food. The purpose of this policy is to encourage good sanitation practices and to avoid a general debasement of the food supply.

The FDA policy is reflected in its regulations, which prohibit the mixing of food containing defects in excess of a defect action level with another lot of food, regardless of the defect level of the final food (see 21 CFR §110.110 (d)). Similarly, in the preamble to the final regulation governing poisonous or deleterious substances in food, FDA rejected requests to permit blending and stated that "the agency's longstanding prohibition against 'blending' remains in effect" (see 42 FR 52814). The FDA prohibition on blending was upheld by the courts in Sugarman v. Forbragd, 267 F. Supp. 817, Northern District of California, 1967.

In a few instances over the past 20 years, involving unusual circumstances, FDA has permitted blending for a limited time period of certain lots of adulterated food for use in animal feed, subject to very strict conditions. The most recent example is FDA's October 1988 Policy Memorandum permitting blending of aflatoxin contaminated corn for animal feed use only. As food manufacturers, this policy is not available to corn refiners. Conditions attached to this limited exception are:

- A written plan outlining the proposed blending must be submitted in advance
- Specific FDA or state approval of the written plan must be obtained
- FDA or appropriate state officials must be physically present during the blending operations
- Corn to be blended may not have been previously shipped in interstate commerce
- The blended product may only be used for animal feed, even if the aflatoxin level of the finished product is below 20 ppb

We hope that this information will be helpful to the Committee.

Sincerely,

Kyd D. Brenner
Director of Public Affairs

cc: W. Kirk Miller

DAN GLICKMAN, KANSAS
CHAIRMAN
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EX OFFICIO MEMBER
CLIFF HUMPHREY
MINORITY CONSULTANT

**U.S. House of Representatives**
**Committee on Agriculture**
**Subcommittee on Wheat, Soybeans, and Feed Grains**
**Room 1301, Longworth House Office Building**
**Washington, DC 20515**

March 30, 1989

To: Members and Staff
Wheat, Soybeans, and Feed Grains Subcommittee

From: Dan Glickman

Subject: background material for April 4 Subcommittee hearing

**********

On Tuesday, April 4 at 9:30 a.m. in Room 1302, the Subcommittee will hold a public hearing on the question of aflatoxin contamination of the 1988 corn crop.

As I am sure you are aware, this subject has received considerable media attention in the last few weeks, generating controversy among some those who believe the incidence of aflatoxin is widespread and those who believe such reports overstate the seriousness of the problem. The witnesses who will testify next week will address this wide range of views.

The Federal Grain Inspection Service has been evaluating new testing techniques for aflatoxin. Administrator Miller will discuss these efforts and the present FGIS testing for aflatoxin.

Drs. Tannenbaum and Livingston are consultants to a company, Vicam, which has developed a new test for aflatoxin. Also, Dr. Tannenbaum has an extensive background on scientific research into aflatoxin and its threat to human health.

Mr. Leonard Stoloff is a chemist retired from the Food and Drug Administration. During his career, he also concentrated on the question of aflatoxin's effect on human health. Unlike Drs. Tannenbaum and Livingston, however, Mr. Stoloff concludes that while aflatoxin is a threat to human health, it is not as carcinogenic as other research concludes.

Mr. Ron Leonard's organization, the Community Nutrition Institution, was instrumental in legal action against the Food and Drug Administration which resulted in the present FDA regulations with respect to aflatoxin.

The final panel of witnesses will consist of representatives of various sectors of the grain trade and food processing industry.

In addition to a draft witness list, I am attaching an extensive set of background materials on this issue, including copies of recent newspaper and magazine articles. I hope this material will help prepare you for the hearing.

If you have any questions, please call Greg Frazier at 5-1494.

Tuesday, April 4, 1989

(draft)

WHEAT, SOYBEANS, AND FEED GRAINS SUBCOMMITTEE, Public Hearing, 1302 Longworth House Office Building

Subject: Review of the incidence of aflatoxin in the 1988 corn crop and related issues

W I T N E S S E S

9:30 a.m.

1. Mr. W. Kirk Miller, Administrator, Federal Grain Inspection Service, Department of Agriculture, Washington, D. C.

   aac. by: Mr. Steven Tanner, Assistant to the Administrator for Technology, Federal Grain Inspection Service, Department of Agriculture, Washington, D. C.

2. panel

   Dr. Steve Tannenbaum, Professor of Chemistry and Toxicology, Massachusetts Institute of Technology, Cambridge, Massachusetts

   Dr. David Livingston, Harvard Medical School and Consultant to Vicam, Inc., Cambridge, Massachusetts

   Mr. Leonard Stoloff, Consultant, Silver Spring, Maryland

   Mr. Ron Leonard, Executive Director, Community Nutrition Institute, Washington, D. C.

3. panel

   Representative of the Corn Refiners Association

   Representatives of the National Grain and Feed Association representing the grain storage, processing, and exporting industries

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date OCT - 4 1988

From Associate Commissioner of Regulatory Affairs, (HFC-1)

Subject Regulation of Aflatoxins in Food and Feed

To Regional Food and Drug Directors and District Directors

As a result of this year's severe drought and late rainfalls, the 1988 corn crop may contain higher than normal levels of the mold-produced toxins, aflatoxins. Because of this increase in potential for contaminantion, the agency is being asked by State and industry officials about the status of aflatoxin action levels, the possibility of regulatory relief (e.g. blending, ammoniation), and in general terms how FDA intends to deal with the situation. This memorandum reviews agency policy regarding the regulation of aflatoxin-contaminated corn for food and feed use in order to assure a common understanding of the statutory basis for regulating such commodities and to provide a basis for consistent guidance to FDA field offices and to the affected States and industry.

CNI v. Young

As FDA stated in the Federal Register of February 19, 1988 (53 FR 5043):

> On May 15, 1987, the D.C. Circuit held that FDA action levels are legislative rules rather than general statements of policy within the meaning of the APA (5 U.S.C. 551(5)) and, therefore, must be promulgated in accordance with the notice and comment procedures of that statute. CNI v. Young, 818 F.2d 943 (D.C. Cir. 1987). Because FDA's action levels were issued without such procedures, the court found the action levels to be "invalid." Id. at 950.

FDA issued the FR notice in response to the circuit court's decision and to publicly state that action levels for added poisonous or deleterious substances are not binding on the courts, the public (including industry), or FDA (including agency employees). Thus, when FDA encounters such an added substance in a food or feed, it can decide to take or not to take regulatory action on the finding, whether the level is above or below the action level. Nonetheless, and as stated in my note of May 5, 1988, to regional directors, "current action levels still represent the best guidance available on the levels of chemical and other contaminants the agency would normally consider to be of regulatory interest." Thus, in the case of aflatoxins, this statement directed FDA field offices to continue to use action levels as guidance for assessing whether regulatory actions are likely to be supported.

2



Regulation of Aflatoxins

Action Levels: Aflatoxins are added poisonous or deleterious substances which, depending upon their level in food or feed, may make food or feed adulterated under section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (FFDCA). This section states that a food (or feed) is deemed to be adulterated if it contains such a substance "which may render [the food (or feed)] injurious to health," and it is the government that must show that there is a reasonable possibility of harm. Thus, the action levels for aflatoxins were intended to represent the levels of contamination at which, in the agency's view, the government could satisfy the "may be injurious" test.

Specifically the agency believed and continues to believe that levels of aflatoxins in excess of 20 parts per billion (ppb) for foods for human consumption, e.g., corn, that are directly susceptible to aflatoxin contamination may render the food commodities injurious to human health. The situation with the action level for aflatoxins in corn as a feedstuff is more complex. In 1980 and 1983, because of severe aflatoxin contamination of the corn crop, FDA allowed the interstate shipment of feed corn containing up to 100 ppb aflatoxins provided the agency was assured that the corn was fed only to mature beef cattle, swine, and poultry. Such assurance was provided by FDA-approved control plans developed and carried out by cooperating state agencies. The 100 ppb limit for aflatoxins in feed corn was based on available scientific evidence and expert witnesses to substantiate that a charge of adulteration under section 402(a)(1) could be supported when corn containing less than 100 ppb aflatoxins intended for mature beef cattle, swine, or poultry.

More recently, the Center for Veterinary Medicine (CVM) has been able to further define subgroups within the mature beef cattle and swine class for which levels of aflatoxins higher than 100 ppb may be necessary to support a "may be injurious to health" charge of adulteration under section 402(a)(1) of the FFDCA. Thus, for finishing swine (e.g., about 100 lbs or greater) aflatoxin levels in excess of 200 ppb could support the charge, while levels above 300 ppb aflatoxins in corn could support a 402(a)(1) charge when the corn is intended for finishing (i.e., feedlot) beef cattle. For breeding beef cattle, breeding swine, and mature poultry, corn containing aflatoxins in excess of 100 ppb aflatoxins could support the adulteration charge.

Recent research has served to better define and confirm that aflatoxin levels of approximately 20 ppb in a dairy fed can result in aflatoxin residues in milk approaching 0.5 ppb. This was and continues to be the reason FDA's 20 ppb action level for feed corn for dairy cattle has not changed. Further, the agency is not aware of any new evidence available that would warrant an immediate change in the 0.5 ppb action level for aflatoxin residues in milk.

For FDA's enforcement activities, and in advising and working with the States and industry on aflatoxin-corn regulatory issues, it is important that FDA's regulatory strategy for aflatoxins be understood. As stated previously the strategy is premised on the fact that FDA must be able to show that any finding of aflatoxins that we decide warrants enforcement action can support a "may be injurious to health" charge.

3



Accordingly, CVM and the Center for Food Safety and Applied Nutrtion (CFSAN) are confident that enforcement action can be supported in cases involving aflatoxin-contaminated corn shipped in interstate commerce when:

1. Corn containing in excess of 20 ppb aflatoxins is destined for food use by humans, for feed use by immature animals (including immature poultry) and by dairy animals, or its destination is not known.

2. Corn containing in excess of 100 ppb aflatoxins is destined for breeding cattle, breeding swine, or mature poultry.

3. Corn containing in excess of 200 ppb aflatoxins is destined for finishing swine (e.g., 100 lbs or greater).

4. Corn containing in excess of 300 ppb aflatoxins is destined for finishing (i.e., feedlot) beef cattle.

CFSAN is also confident that regulatory action can be supported against milk or milk products being sold in interstate commerce and that contain at least 0.5 ppb aflatoxin residue. FDA expects enforcement actions for milk which exceeds 0.5 ppb to be dealth with under the Interstate Milk Shippers Program. When such levels are encountered following investigation into the feed source of the aflatoxin is indicated.

All these action levels must be viewed and used as guidance rather than definitive, "bright line" standards. Thus, there may be situations where circumstances warrant consideration of enforcement action at below an action level or enforcement action is not pursued when an action level is exceeded.

In considering enforcement action for aflatoxin levels below an action level, the districts must take into account the agency's ability to support the adulteration charge that will be included in the complaint. If a district believes that enforcement action is warranted at levels below an action level, then the recommendation to the appropriate Center should include all compelling reasons for pursuing such action.

Implementation of the above regulatory position can be achieved through State control plans, FDA or State agreements with food/feed trade associations or individual companies, or any other mechanism an FDA regional/district office believes will ensure that corn in interstate commerce will not be adulterated within the meaning of section 402(a)(1).

Blending Policy: In order to deal with the possibly higher than normal aflatoxin level in the 1988 corn crop, we plan to exercise our enforcement discretion to refrain from objecting to the blending of aflatoxin adulterated corn with non-adulterated corn to produce a blended mixture of corn below the above listed action levels for animal feed usage only. This policy only applies to corn from the 1988 crop and for FDA not to object to such blending, all the following conditions should be met:

**U.S. Feed Grains Council**

1400 K Street N.W. • Suite 1200 • Washington D.C. 20005

Telephone 202 • 789 • 0789
Telex 440064 USFG UI
Cable USFEED

**MEMORANDUM**

DATE: February 23, 1989

TO: All Overseas Offices

FROM: Ken Hobbie, Executive Director of International Market Development

SUBJECT: Aflatoxin Concerns

Please find attached an article which appeared today on the front page of the U.S. Wall Street Journal concerning aflatoxin in U.S. corn. We have also attached a copy of the talking points being used by PGC/W concerning this article.

As you are all aware, when concerns about aflatoxin surfaced this past fall the Council went to great lengths to keep all overseas offices informed of the severity of the situation in the U.S. and the regulations governing its appearance in exports of U.S. feed grains. In addition, we sent teams to overseas markets as necessary to address customer concerns, and spoke to the issue as appropriate through the TEA Market Education program and other ongoing market development activities.

Recently we have felt that the aflatoxin concern has, for the most part, not been a key issue in the minds of our customers when deciding to purchase U.S. corn. The attached article, if circulated in the international press, may change this perception considerably. We ask each of you to pay particular attention to this area in your day-to-day transactions with U.S. feed grain users in your country, and to advise your International Director immediately if aflatoxin contamination in U.S. feed grains again becomes a major quality issue in your market. Should this occur we are prepared to work with you in formulating an appropriate market development response.

If you have any questions, please refer them to your respective IDO at once.

Regards.

KH/dwf

Attachments

TALKING POINTS ON AFLATOXIN

1. The incidence of aflatoxin in the 1988 corn crop is a minor problem that is controllable and does not pose a health threat to our export customers.

2. The Food and Drug Administration has set the following limits for aflatoxin in corn marketed in the United States:

   20 ppb for corn marketed for consumption by humans, dairy cattle, poultry, immature animals or if the ultimate destination of the corn is unknown, which includes export channels.
   100 ppb for breeding cattle, or swine
   200 ppb for finishing swine
   300 ppb for finishing beef cattle on feedlots

3. There are channels for corn with greater levels of contamination. Farmers can destroy contaminated corn and receive disaster payments for that corn. They are not forced to market contaminated corn.

4. 1988 crop corn that is currently under government loan had to meet the 20 ppb requirement before it was placed under loan. So corn now in storage that is under loan was tested and is within the 20 ppb level.

5. There are safeguards to prevent contaminated corn from getting into export channels. First, it is illegal, under interstate commerce laws, to transport grain with more than 20 ppb across state lines if it is destined for human consumption or its destination is unknown. Second, although FGIS does not routinely test exported corn, foreign buyers who continue to be concerned about aflatoxin contamination can request such a test be done by FGIS. Also, many foreign buyers, including the Soviets and the Japanese, have been rigorously testing corn coming from the United States. The Soviet Union requires corn shipments to meet a 5 ppb test. There have been no rejections by foreign buyers of 1988 crop corn due to incidence of aflatoxin.

6. The incidence of aflatoxin in the 1988 is not as widespread as media reports have led some to believe. A USDA state crop survey indicates that only about 7 percent of the crop tested positive for aflatoxin.

7. The blacklight test for aflatoxin is generally used as a screening test only. The present of glowing corn kernels does not necessarily indicate aflatoxin. In fact, test studies have shown than over 70 percent of samples that contain "glowers" do not have aflatoxin.

8. The U.S. Feed Grains Council alerted export customers to the potential problem of aflatoxin last fall, explained the U.S. regulatory system and advised them that they could request FGIS testing if they felt the system currently in place did not adequately meet their needs.

U.S. Feed Grains Council
1400 K Street N.W. • Suite 1200 • Washington D.C. 20005
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MEMORANDUM

DATE: September 22, 1988

TO: All Overseas Offices

FROM: Ken Hobbie

SUBJECT: Aflatoxin

As the 1988 corn harvest gets underway, there have been isolated reports of aflatoxin in corn being delivered to country elevators. Some recent articles in the U.S. press have also focused on aflatoxin and the drought. These articles have, unfortunately, often contained erroneous information and have taken an alarmist approach with little or no basis for doing so.

To keep you informed and help you deal with concerned customers, the Planning and Trade Servicing Department put together the following background information on aflatoxin. This document is being provided to you for internal use only and should not be circulated outside the office.

Definition

Aflatoxin B1, sometimes present in corn, is a known carcinogen. Ten to twenty parts per billion (ppb) of aflatoxin consumed regularly by sensitive young animals can result in liver cancer, whereas in older animals only minimal effects may occur. No animals are known to be immune. Aflatoxin has been implicated in liver cancer in humans.

Climatic Conditions Which Promote Aflatoxin Growth

Aspergillus flavus and A. parasiticus are ubiquitous in soil and on decaying plant material, causing heating and decay of stored grain and, under certain conditions, commonly invade corn in the field in the southeast and the southern Corn Belt of the USA. These fungi do not, in most cases, produce aflatoxin. To do so, very specific moisture and temperature conditions must be present. Aspergillus Flavus produces aflatoxins in corn starting at a moisture content of about 18% i.e., in equilibrium with 85% relative humidity and at temperatures between 56 and 116 degrees Fahrenheit.

These fungi are serious problems in subtropical and tropical countries where maize is an important part of the human diet. Under certain conditions aflatoxin is produced in corn as the kernels are developing on the ears. Aflatoxin production by Aspergillus Flavus is more likely following damage of ears by insects, birds, hail, early frost, drought stress, or other unfavorable weather. Roasting, ammoniation at ambient temperatures, and some microbial treatments may sharply reduce but not necessarily eliminate the aflatoxin content.

Aflatoxin Detection and FDA Action Levels

Methods for aflatoxin analysis fall into two categories: rapid screening procedures determining the presence or absence of aflatoxin (fluorometric iodine rapid screening and minicolumn tests) and laboratory procedures quantifying the actual amounts of toxin (thin-layer chromatography, gas-liquid chromatography, or high-pressure liquid chromatography tests). Various commercial, state, and federal laboratories perform aflatoxin analyses on a fee basis. The FDA action level for aflatoxin is twenty ppb for both domestic and export markets. In other words, it is unlawful to ship grain interstate or export grain that tests over 20 ppb. Grain that tests over 20 ppb will not be allowed to be used in the production of human food or dairy feed products.

FGIS will run aflatoxin tests only if requested. If official FGIS sampling and testing results indicate an aflatoxin level of 20 ppb or above, then FGIS will report the findings to the FDA. No corn containing over 20 ppb aflatoxin can be exported unless the foreign buyer advises FDA that they do not object to the high aflatoxin level in that shipment. The Food and Drug Administration will then seize the grain and consider diverting it, on a case by case basis, to cattle and hog producers, depending upon the level of contamination. If the grain is unsuitable for livestock use, then the FDA will make arrangements for it to be destroyed.

Predictability of Aflatoxin Incidence in 1988 Crop

The consensus from most experts is that it is still too early to accurately predict the likelihood of aflatoxin showing up in the 1988 U.S. crop. The problem is that there are too many variables which could affect the crop's condition (i.e. wet harvest conditions, hail, etc.) and lead to the presence or absence of aflatoxin.

Needless to say, the FDA and the agribusiness community is very alert to the possibility of aflatoxin incidence in a given crop and, as a result, we can be assured that testing programs will be in place this fall. While the concern about aflatoxin is real and pre-conditions for its possible occurrence are present, there is no current evidence that its incidence on the 1988 crop is abnormal.

Conclusion

We have seen a keen interest in the aflatoxin issue from participants at several market education workshops. We anticipate more inquires about aflatoxin from foreign customers, especially in light of the current drought situation and recent press reports. The foreign buyer wants to know what control procedures the U.S. is using to insure that grain export shipments will be aflatoxin - free. It will be necessary to reassure them that proper controls are in place and they should expect to receive good quality feed grains from the U.S. If individual customers are concerned about possible aflatoxin in their shipments, official FGIS testing may be requested as part of the contract.

Please keep us informed if there are questions or concerns raised by your contacts about this issue.

## Detection of Aflatoxin

There are several methods for detecting aflatoxin in corn. Some are presumptive (qualitative) tests, indicating only that the toxin may be present, others are quantitative, revealing the actual level of aflatoxin in the test sample.

### Black-light

The black-light (ultraviolet at 366 nm) causes certain compounds associated with active fungi to fluoresce (glow) bright green-yellow (BGYF). In a black-light test, whole or preferable cracked kernels are illuminated with UV light. The presence of "glowers" is not an assurance of aflatoxin, only an indication that the sample should be analyzed further. Conversely, absence of "glowers" is not absolute proof of absence of aflatoxin. Elevators use black-light screening to sort clear lots from suspect ones.

In 1983 tests, the black-light missed (found no glowers) in 11% of lots containing over 20 ppb when 4 lb samples were used, and missed none when 24 lb samples were used. The smaller samples had 33% false positives (glower but no aflatoxin) while the large samples had 55% false positives. This underscores the need to take large representative samples when inspecting for mycotoxins and to follow up a positive black light test with an analysis. Most experts recommend a 10 lb minimum sample size. It is vital that personnel performing the black light screening test be thoroughly trained in the procedure in order to avoid many false positives.

### Minicolumn

This method will detect aflatoxin levels in excess of 10 ppb. A sample of corn can be processed in 20 to 60 minutes. A concentrated corn extract is passed through a minicolumn tube that contains layers of alumina and silica gel. After treatment with a developing solution, a fluorescent blue band appears. The color intensity of the blue fluorescence is directly proportional to the level of aflatoxin, but in most cases the minicolumn test is used only to identify lots with concentrations in excess of 20 ppb.

### Chromatography

This methods involves extraction with chloroform followed by purification on a silica gel column for quantitative thin layer chromatography. Since this method determines actual levels of aflatoxin in a sample, it must be performed in a well equipped laboratory.

### Sampling

The importance of an accurate and representative sample cannot be stressed enough. The weight represented by 20 ppb is equivalent to only 20 kernels in a railcar (3500 bushels). Because aflatoxin is not evenly distributed in all kernels, the collection of a large sample (preferably 10 lbs and certainly no smaller than 5 lbs) is essential. Black light the entire sample. Subdivision into smaller size for minicolumn or chromatography should be done after coarse grinding and mixing, not on the whole kernels.

There is no practical approved method for detoxifying large amounts of contaminated corn. Dryer heat will not break down mycotoxins. Rigorous cleaning will remove broken particles (fines) which are more susceptible to mold invasion. This may lower mycotoxin levels somewhat. Cleaning is first

done on the combine. A rotary cleaner is effective in removing remaining fines, provided flow rates are held below the rated capacity of the cleaner.

If corn is obviously moldy in the field, harvest it promptly. Clean (remove fines) before putting into storage. Do not mix mold or known aflatoxin-contaminated corn with sound corn.

Field molded corn above 20% moisture should not be low temperature dried. This is a slow drying process, which can allow the aflatoxin contamination to get worse. On the other hand, droughty corn is brittle and prone to breakage. Grain temperatures in excess of 149 degrees will aggravate the breakage problem. Grain management in stress conditions is a tradeoff between breakage potential and mold damage. Dry the shelled corn to at least 15% moisture as rapidly as possible but not longer than 24-48 hours after harvest. Safe, long-term storage can be achieved at a uniform moisture content of 13%. Slow drying accomplished by low heat or natural air drying is widely used in some regions but the grain can be no higher than 20-21% moisture in full bin drying. In some cases, high temperature drying could be used until the grain reaches 20-21% moisture followed by low heat drying to 13% moisture.

Cool the grain after drying and maintain dry storage conditions. Where possible, continue cooling until grain temperature reaches 2-5 degrees Centigrade.

Holding wet grain, even for short periods (e.g. overnight in a wagon) is not recommended since considerable amounts of aflatoxin can be produced in a short period of time. Aflatoxin concentrations can increase even without a noticeable change in the visual moldiness of kernels.

Clean the bins thoroughly before storage to remove dirt, dust, crop debris, chaff, and cracked or broken kernels. Store in water tight structures that are free from insects and rodents. Continue periodic aeration and probing for "hot spots" at intervals of one to four weeks throughout the storage period.

Several organic acids (propionic, isobutyric, acetic, and mixtures of these with ammonium isobutyrate) are registered for use on high moisture grain in storage and sold under various trade names. Although these acids will not remove any aflatoxins previously formed in the grain, they will prevent growth of fungi if properly applied. Grain treated with an organic acid can be used only for livestock and poultry feed. The ensiling process when corn silage is made will stop further aflatoxin production but does not destroy toxin formed prior to the ensiling process. Spoiled or mold corn silage should not be fed to livestock. There are no fungicides currently labeled for use on stored corn in Iowa.

Blending lots with a high level of contamination with uncontaminated corn is not permissible if the corn is to enter interstate commerce. With careful sampling and analysis, most contaminated lots of corn can be used locally for feed. Very thorough mixing is necessary because blending does not diminish the aflatoxin concentration in affected kernels, it only dilutes the number of contaminated kernels per unit of weight. Both lots should be dry and clean in order to avoid the inevitable segregation by moisture and particle size.

U.S. Feed Grains Council

[illegible]

Telephone 202 [illegible]
Telex [illegible]
Cable [illegible]

Typed this for OC
sent out from
Moscow

MEMORANDUM

DATE: November 18, 1988

TO: All Overseas Offices

FROM: Ken Hobbie

SUBJECT: U.S. Corn Crop Survey Results on Aflatoxin

We have been gathering information from Department of Agriculture officials in the key corn producing states to give us a more complete picture of the incidence of aflatoxin throughout the corn belt. As you might have expected, recent crop surveys indicate that the presence of aflatoxin in new crop corn is decreasing. The summary of the crop survey results indicate that the majority of new crop corn contains 7 percent or less of aflatoxin contamination. These results certainly are welcome news to all of us in light of the media's distortion of the problem earlier this fall when projections of aflatoxin levels where biased and incomplete. It is reassuring to note that these results indicate that there should be little problem finding domestic market uses for most aflatoxin corn under the new FDA guidelines, thus assuring the availability of high quality corn exports to our foreign customers.

While there is some variability between states and isolated regions in the amount of aflatoxin in corn, grain throughout the entire country is relatively free of aflatoxin contamination. We can safely assume that we will be able to meet the quality and supply demands of our domestic feed industry, industrial corn and seed sectors, and our export customers.

There are state producer grower groups that are independently promoting their own state's corn quality characteristics this year. The Council's position is that we should promote the quality and dependability of the U.S. marketing system and the supply of U.S. corn at the national level. We do not want to promote grain procurement practices that specify grain purchases from specific states. One obvious reason is that through the complex U.S. marketing and handling system feed grains will undoubtly be blended from different growing regions. It would be terribly cost prohibitive for handlers to segregate grain by origin, although it would be possible if buyers are willing to pay for these costs. Therefore, the Council is not encouraging the advertising of corn from specific states.

As many of you are aware, FGIS will test grain for export for aflatoxin if requested. Many overseas customers know that they can negotiate with U.S. suppliers to include aflatoxin testing as part of their purchase contract. The Soviet Union, for example, requires all U.S. corn shipments bound for the USSR to be certified under 5 ppb for aflatoxin in their purchase contracts. The overseas buyer must be willing to negotiate the premiums to cover the costs of testing and aflatoxin level guarantees in purchase contracts with their U.S. suppliers.

The Council certainly views the aflatoxin issue with deep concern and we have continued to monitor the situation very closely. Please keep us advised of any complaints about aflatoxin that you may uncover from trade contacts in your region.

KH/kva/tat/11/18/88
cc: Richard Krajeck
Allen Terhaar
Ken Stephens

Questions and Answers

1) Q: Does the United States Federal Grain Inspection Service automatically inspect for aflatoxin in all export shipments?

A: No. FGIS will inspect grain for aflatoxin levels only if the buyer requests testing. Regular U.S. grain customers almost always request official aflatoxin testing on corn shipments.

2) Q: Is the black-light test quantitative for aflatoxin levels?

A: No. The black-light causes certain compounds associated with active fungi to glow bright green-yellow. The presence of "glowers" is not an assurance of aflatoxin, only an indication that the sample should be analysed further. Grain elevators use black-light screening to sort clear lots from suspect ones. Test studies have shown that over 70 percent of samples that contain "glowers" do not have aflatoxin.

3) Q: What types of tests are currently being used to quantify aflatoxin levels in grain?

A: Minicolumn - test will detect aflatoxin levels in excess of 10 ppb. In most cases the minicolumn test is used only to identify lots with concentrations in excess of 20ppb.
Chromatography - This test method will determine actual levels of aflatoxin in a sample. The procedure requires a well equipped laboratory.

4) Q: How does an individual sample grain to determine accurate aflatoxin levels?

A: The importance of an accurate and representative sample cannot be stressed enough. The weight represented by 20 ppb is equivalent to only 20 kernels in a 89 metric ton lot (approx. 1 rail car). Because aflatoxin is not evenly distributed in all kernels, the collection of a large sample (preferably 4.5kg and certainly no smaller than 2.25kg) is essential. Black light the entire sample. Subdivision into smaller size for minicolumn or chromatography should be done after coarse grinding and mixing, not on the whole kernels.

5) Q: What governmental agency in the United States regulates and controls commercial use of aflatoxin contaminated grain?

A: The Food and Drug Administration has strict guidelines for the commercial use of aflatoxin contaminated grain and other nut commodity products.

6) Q: What are the new FDA limits for aflatoxin in corn used in livestock feeding?

A: --20ppb for corn marketed for consumption by humans, dairy cattle, poultry, immature animals or if the ultimate destination of the corn is unknown;
--100ppb for breeding cattle, or swine;
--200ppb for finishing swine; and
--300ppb for finishing beef cattle on feedlots.

7) Q: Do the new FDA limits for aflatoxin affect grain for export?

A: No. The new limits are action levels for aflatoxin in corn used only for domestic livestock feeding.

8) Q: How will these new levels affect carcinogen residues in meat products from the United States?

A: The FDA, in setting levels in the range of 100 to 300, was guided by research on how well livestock stand short-term exposure to aflatoxin. "At this range only dairy cattle would pass the aflatoxin onto the consumer," said Elizabeth Campbell, chief of the FDA's guidelines and compliance research branch. Research data indicate that "these levels wouldn't result in any aflatoxin residues in meat or eggs," Campbell added.

9) Q: What is the reported level (percentages) of aflatoxin incidence in this years' corn crop?

A: Knowing that in most cases the worst of the corn crop is harvested first, most experts believe that the final percentages of aflatoxin contamination will be less than the early reports. In Iowa, Charles Hurburgh, spokesman for the state department of agriculture's Veterinary Medicine Laboratory, said no indication of test results would be released until all results were tabulated.

The Indiana State Chemists Office has tested 103 samples of corn, with 10 to 14 pct showing more than the minimum 20 ppb consider fit for human consumption. Most of the samples with positive readings tested very close to 20ppb and there was a cluster around 50 ppb. The highest reading in the early Indiana tests was 129 ppb.

The Illinois Department of Agriculture laboratories have tested 327 random samples for aflatoxin and of that, 35.8 pct, or 117 samples, were above 20 ppb. Of the 117 positive samples, 85 had readings of 20 to 100 ppb, and 32 were more than 100 ppb. Only 6 samples were above 300 ppb. The corn harvest is 40% complete in the state of Illinois.

United States Department of Agriculture

Agricultural Stabilization and Conservation Service

Post Office Box 419205
Kansas City, Missouri 64141-0205

September 23, 1988

WAREHOUSEMAN'S LETTER C-33/T-33

TO : All Warehousemen Approved Under the Uniform Grain Storage Agreement (UGSA)

SUBJECT: Commodity Credit Corporation (CCC) Policies Regarding CCC-Owned Inventory and Aflatoxin

Several states, where the 1988 corn harvest has begun, are reporting the presence of aflatoxin in newly harvested corn. Aflatoxin, a fungus mold, is toxic to both humans and animals. Corn containing aflatoxin at a level equal to or greater than 20 parts per billion (ppb) is not eligible for price support loan programs.

In areas where aflatoxin is known to be present, CCC will draw samples of farm-stored corn to determine the presence of aflatoxin. However, corn harvest has already begun in many areas and some farm-stored loans may have already been made. If a farm-stored loan is found to be contaminated with aflatoxin, the loan will be called and the borrower will be required to repay the outstanding loan amount plus accrued interest.

Farm-stored loan corn delivered to CCC which contains aflatoxin equal to or greater than 20 ppb will not be accepted by CCC in settlement of loan obligations regardless of whether or not the corn was tested before the loan was made. The receiving warehouseman shall notify the county ASCS office that issued the commodity delivery notice (Form CCC-691) of such aflatoxin determinations. Under certain circumstances producers will be eligible for disaster payments if the contaminated corn is destroyed.

CCC will disburse warehouse-stored loans to producers on eligible corn based on the quality and quantity shown on the warehouse receipt issued by the receiving warehouseman.

CCC will continue to make its grain inventory available to interested parties through cash sales, exchanges for commodity certificates, swaps, the Emergency Feed Assistance Program (EFAP), and other methods of disposition.

CCC's policies and the warehouseman's responsibilities for the handling and storage of grain under the Uniform Grain Storage Agreement (UGSA) as it pertains to aflatoxin is as follows:

(1) A warehouseman's responsibility is based on the quality and quantity stated on the warehouse receipt as of the date of deposit in the warehouse. The storing warehouseman will be responsible under the UGSA for maintaining the condition of the grain while in storage.

(2) The determination of weights, grades, and quality for grain both inbound and outbound will be in accordance with Section III of the UGSA.

(3) In the execution of a CCC reconcentration loading order the delivery of corn containing aflatoxin at a level equal to or greater than 20 ppb will be rejected by CCC back to the shipping warehouseman in accordance with Section VII, Paragraph F-5 of the UGSA. Rejected corn and any resulting costs, including transportation and demurrage, will be for the account of the shipping warehouseman.

(4) The warehouseman is responsible for loading out and delivering EFAP grain in accordance with Warehouseman's Letter C-32/T-32 dated August 30, 1988, and any quality differences that arise shall be settled between the warehouseman and the producer/buyer. Under no circumstances will CCC be responsible for any costs/liabilities arising from a warehouseman delivering aflatoxin contaminated corn.

5) CCC inventories are made available for delivery instore through cash sales, exchanges for commodity certificates, and swaps, and are based on the warehouse receipt(s) quality and quantity as stated by the storing warehouseman. Any quantity and quality differences that arise shall be settled between the storing warehouseman and the contractor no matter if the contractor is the storing warehouseman or a third party or if the storing warehouseman has reconsigned corn from a third party. Under no circumstances will CCC be responsible for any costs/liabilities arising from the warehouseman delivering aflatoxin contaminated corn.

Any further questions may be referred to the Warehouse License & Contract Division, Kansas City Commodity Office, Post Office Box 419205, Kansas City, Missouri 64141-0205, telephone (816) 926-6446.

Norman D. Houser

Norman D. Houser
Director

National Grain and Feed Association

April 5, 1989

The Honorable Dan Glickman
U.S. House of Representatives
Washington, D.C., 20515

Dear Congressman Glickman:

The National Grain and Feed Association is very concerned about several serious inaccurate statements concerning the alleged legality of blending of corn containing aflatoxin with "clean" corn made during the April 4th hearing of the House Subcommittee on Wheat, Soybeans and Feed Grains. In addition, testimony and subsequent questioning of some witnesses left the erroneous impression that blending of corn containing aflatoxin is a routine practice within the industry. That most emphatically is not the case. Unfortunately, these inaccuracies have been repeated in press reports of the hearing.

We want to take this opportunity, as we did in response to questions from Chairman Glickman following our testimony at the conclusion of the hearing, to correct the record immediately. Enclosed you will find documentation from the Food and Drug Administration and the Federal Grain Inspection Service substantiating the following facts:

■ First, the blending of corn containing aflatoxin with corn that does not contain aflatoxin is illegal under Section 402 (a)(1) of the Federal Food, Drug and Cosmetic Act. FDA deems such blending to be adulteration under the meaning of the Act and can seize and condemn such corn, a fact well known within the industry. The only exception under which corn containing aflatoxin can be blended with other corn and sold in interstate domestic commerce is governed by the Food and Drug Administration's October 4, 1988 Memorandum concerning the "Regulation of Aflatoxins in Food and Feed," a copy of which is enclosed. FDA requires any company considering such blending to notify FDA, submit and obtain FDA approval of a specific plan on how the blending is to be done, and have FDA inspectors on-site to supervise the actual blending. Further, such blended corn cannot have been shipped into interstate commerce prior to the approval of the blending plan. Finally, the resulting blended mixture may be directed to FDA-approved feed uses, but is strictly prohibited from being diverted into human food or into feed for lactating dairy animals **even if** it contains less than the 20 parts per billion aflatoxin level normally permitted by FDA for those uses.

725 15th St., N.W. ● Washington, D.C. 20005 ● (202) 783-2024

■ Second, the Federal Grain Inspection Service is required under a Memorandum of Understanding with FDA, dated April 9, 1986, to notify FDA immediately if it detects corn containing aflatoxin exceeding FDA-approved levels through official lot inspections and special submitted sample inspections where the carrier is identified. The FDA-FGIS Memorandum of Understanding is enclosed, as are two other FGIS documents attesting to this procedure, with pertinent sections highlighted. Thus, there is a well-established system to foster communication and regulatory coordination between FDA and FGIS concerning aflatoxin.

■ Third, exports of corn are governed specifically by Section 801(d)(1) of the Federal Food Drug and Cosmetic Act. The Act prohibits interstate shipments of corn exceeding FDA's enforcement levels unless they meet the following four conditions: 1) They are in accordance with the specifications of the foreign buyer; 2) They are not in conflict with the laws of the importing country; 3) They are clearly labeled as intended for export; and 4) They are not subsequently diverted into domestic commerce. A copy of this section of the Act is enclosed.

Information published by the National Grain and Feed Association notifying the grain and feed industry of these policies and procedures is enclosed. State and Regional Grain and Feed Associations in areas affected by aflatoxin have published this same information. We can assure you that this is the aflatoxin regulatory framework under which our industry has been operating.

We trust these facts will be helpful to you in responding to any of the inaccuracies concerning blending of aflatoxin corn that unfortunately were conveyed during the Subcommittee's hearing. We would be pleased to respond to any other questions you may have on this issue.

Sincerely yours,

Kendell W. Keith
Executive Vice President

cc: Members of the House Wheat, Soybeans and Feed Grains Subcommittee
The Honorable E. Kika de la Garza
The Honorable Edward Madigan
The Honorable Commissioner Frank Young
The Honorable Clayton K. Yeutter
W. Kirk Miller

HFKIL 2, 89
WASH POST

INGTON POST

# Tainted Corn Routinely Mixed, Sold

## *U.S. Allows Carcinogenic Mold to Be Blended With Clean Kernels*

By Philip J. Hilts
Washington Post Staff Writer

When corn is contaminated with cancer-causing aflatoxin, it can simply be mixed with clean corn and sold anyway, the head of the Federal Grain Inspection Service, W. Kirk Miller, told a House subcommittee yesterday.

Aflatoxin, one of the most potent carcinogens known, is a natural substance produced by a mold that grows on stored grain. The mold grows most abundantly on drought-weakened corn, and Miller said contamination is higher than usual in corn grown during last summer's drought.

Miller said he does not know how much aflatoxin is passing into the food system but said "we have not seen a problem" other than "management by media hysteria" when the hazard appeared and was reported.

Aflatoxin is believed to cause liver cancer when eaten at low doses over a lifetime. Small amounts occur annually in some corn, milk, cheese and peanuts, but two or three times per decade, when the weather and mold spores conspire, there is a severe outbreak.

Tens of millions of bushels of 1988 corn have been found to be contaminated. In Texas 2 million pounds of contaminated milk, from corn-fed cattle, had to be dumped.

The toxin is made by the mold-called *Aspergillus flavus*. The mold's effects went unrecognized until about 30 years ago. But American corn must now compete in international markets, and foreign customers are demanding tested, cleaner corn.

Over recent years a system of loose regulation has grown up. Only scattered samples of corn are tested, and the federal government has set no legal standard for the amount of aflatoxin allowed in food. Only guidelines have been set, and they do not require the destruction of contaminated corn. Corn that contains dangerous levels of aflatoxin may be mixed with clean corn, thereby bringing the average content [illegible] below the guidelines. [illegible] this, clean corn becomes a health risk," said Rodney Leonard of the Community Nutrition Institute, a consumer advocacy group. "In all other food safety regulations, anytime you mix contaminated food with clean food it is a felony, an illegal act. It makes the total product unacceptable. But not with aflatoxin and corn."

Virtually all contaminated corn is ultimately sold, either for animal feed or mixed and sold for human consumption, Miller said.

He said no one knows how much aflatoxin reaches the U.S. food supply because the tests are so costly he decided not to test extensively to find out. Instead, he said, testing has been focused on shipments to the United States' largest customers—Japan, Mexico and the Soviet Union.

> *"Because of this, clean corn becomes a health risk."*
>
> —Rodney Leonard, Community Nutrition Institute

Miller said corn buyers do more testing than does the government, and he does not know what percentage of corn is tested. In the few scattered samples done by the Agriculture Department and the Food and D[illegible]OA), he said, "v[illegible]blems."

But [illegible] are concerned. Many [illegible] of U.S. corn before [illegible] buy, giving rise to an ironic situation referred to repeatedly in hearings before the House Agriculture subcommittee on wheat, soybeans and feed grains yesterday: The U.S. government protects foreign buyers against aflatoxin-contaminated corn more effectively than it does U.S. citizens.

About 75 percent of corn sold for export is tested. "Our export customers ought to be really happy, because they're getting preferential treatment," said Rep. Dan Glickman (D-Kan.), chairman of the subcommittee.

One reason that the system has not gotten tougher, sooner is that the hazard is not immediately apparent. Acute aflatoxin poisoning can be fatal if large amounts of moldy food are eaten, but those cases are rare. Far more often a problem develops over many decades.

In laboratory tests, all the types of animals so far tested, from mice to monkeys, have gotten cancer from diets that include small amounts of aflatoxin.

In addition, some epidemiological studies show that in areas where high levels of aflatoxins are often found in grains, there is also a high rate of liver cancer.

The FDA has set 20 parts of aflatoxin per billion parts of corn or other crops intended for human or dairy animal consumption as the level at which it may take action. Between 100 and 300 parts per billion are allowed in various kinds of animal feed.

Japan and some European nations have set stricter standards, at levels ranging from zero to 10 parts per billion.

The amount of cancer caused by these levels is not known, but European researchers estimate that 0.5 parts per billion eaten over a lifetime may cause 500 extra cancers per million people.

Generally, the FDA considers one extra cancer per million people as hazardous enough to ban a product.

Miller yesterday spoke about the hazard only in terms of markets for U.S. corn. When asked what Congress could do to help, he said, "You can help me avert management by media hysteria. I am very concerned about the destruction of markets" because of the reports of aflatoxin in corn. "It takes years and years to recover markets that are lost" by such bad publicity, he said.

"Why don't you prevent the hysteria by testing all the corn?" asked Rep. Jim Jontz (D-Ind.).

"It comes down to cost, and who's going to pay," Miller replied. Later, he added, "I personally don't favor mandatory testing."

FDA officials said they do not know how much aflatoxin gets into food products such as corn flakes, corn meal, tortillas and grits. But six of 263 samples tested last fall, or 2 percent, the level was found to be higher than 20 parts per billion.

In 1,650 samples of corn used to feed animals, 95, or about 6 percent, were found higher than 20 parts per billion.

The Agriculture Department's Miller said that about one percent of the tests on corn for export showed levels higher than 20 parts per billion and that this contaminated corn was "blended off" with clean corn and sold.

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Government & Grain

National Grain and Feed Association

Volume XXXX, Number 21, October 6, 1988

# FDA Issues Aflatoxin Enforcement Policy

By Randall C. Gordon
Vice President, Communications and Government Relations
National Grain and Feed Association

The Food and Drug Administration on Oct. 4 released its long-awaited policy memorandum concerning how the agency intends to regulate interstate shipments of corn containing aflatoxin in 1988.

The new policy statement contains a range of limits applicable to corn containing aflatoxin of 20 to 300 parts per billion which, if exceeded in interstate shipments, the agency says it has the scientific data available to support enforcement action. States retain jurisdiction over intrastate shipments, but often adopt FDA's levels.

The FDA policy memorandum, issued to its regional and district offices, is designed to clarify the agency's regulatory stance in the aftermath of a recent court decision that invalidated FDA's use of "action levels" as rigid enforcement criteria. (See Government and Grain, Sept. 8, 1988.)

The legal decision, handed down on May 15, 1987 by the U.S. Court of Appeals for the District of Columbia Circuit, in essence found FDA had used its previous aflatoxin action levels in such a way as to be "legislative rules" rather than "general statements of policy." The court stated that if action levels were to be used as rigid enforcement tools, the agency first would be required to proceed through the normal public-notice-and-comment rulemaking process utilized for most government regulations.

But the appeals court left open the possibility that government agencies could use "guidelines" as a method of exercising regulatory discretion. Said the court: "We recognize that such guidelines have the not inconsiderable benefit of apprising the regulated community of the agency's intentions as well as informing (the industry about) the exercise of discretion by agents and officers in the field. It is beyond question that many such statements are nonbinding in nature and would thus be characterized by a court as interpretive rules or policy statements...."

Following the court ruling, FDA issued a public notice stating that action levels for "added poisonous or deleterious substances are not binding on the courts, the public (including industry) or FDA." Thus, the agency said at the time, when FDA encounters such a substance in food or feed it can (but not necessarily will) decide whether to take regulatory action.

This is the reason FDA, in drafting its new regulatory policy statement concerning aflatoxin, provides a certain degree of flexibility to its regional and district offices to take enforcement action on commodities containing aflatoxin at different levels than those specified by FDA if they deem appropriate. Yet, despite FDA's attempt to clearly comply with the court's decision, the plaintiff that brought suit against the agency -- the Ralph Nader-affiliated Community Nutrition Institute -- already has said it is considering filing legal action again against FDA's newly issued policy.

## FDA's New Aflatoxin Levels

FDA's policy statement contains new aflatoxin levels which, if exceeded in interstate shipments, the agency says it is "confident" enforcement action "can be" supported. Those new levels are as follows:

- Corn containing "in excess" of 20 p.p.b. of aflatoxin that is destined for human food; for feed use by immature animals (including immature poultry, such as broilers) and dairy animals; or if its destination is not known.

- Corn containing "in excess" of 100 p.p.b. of aflatoxin that is destined for breeding cattle, breeding swine or mature poultry (such as laying hens).

- Corn containing "in excess" of 200 p.p.b. of aflatoxin that is destined for finishing swine, which FDA defines as hogs that weigh 100 pounds or more.

- Corn containing "in excess" of 300 p.p.b. of aflatoxin that is destined for finishing beef cattle, such as those in feedlots.

Again, it should be emphasized that FDA's policy memorandum states that the agency has the scientific data available to support regulatory action by its regional or district offices if aflatoxin is present in interstate shipments of corn at levels that exceed these guidelines. The agency itself states in the policy memorandum that its regulatory strategy concerning aflatoxin "is premised on the fact that FDA must be able to show that any finding of aflatoxins that we decide warrants enforcement action can support a 'may be injurious to health' charge." The "may be injurious to health" phrase is the legal predicate contained in Section 402(a)(1) of the Food, Drug and Cosmetic Act on which FDA is authorized to bring enforcement action.

In implementing its new aflatoxin policy, FDA's memorandum provides a certain degree of flexibility to its regional and district offices to bring enforcement action at levels different from those cited by FDA if those local offices deem such action appropriate. But it should be emphasized that FDA's policy memorandum repeatedly cautions the regional and district offices that the preponderance of scientific data that will be necessary to support enforcement actions are at the levels contained in FDA's policy.

"All of these action levels must be viewed and used as guidance rather than as definitive 'bright-line" standards," FDA's policy memorandum states. "Thus, there may be situations where circumstances warrant consideration of enforcement action at (levels) below an action level or (where) enforcement action is not pursued when an action level is exceeded.

"(But) in considering enforcement action for aflatoxin levels below an action level, the district (FDA offices) must take into account the agency's ability to support the adulteration charge....," the policy memorandum states. "If a district believes enforcement action is warranted at levels below an action level, then the recommendation to (FDA) should include all compelling reasons for pursuing such action."

FDA officials have told the National Grain and Feed Association that one instance in which FDA district offices might take enforcement action at levels different than those specified in the policy would be in cases where a company violates the agency's stringent criteria on blending (discussed below).

The FDA policy memorandum grants to its regional, district and local offices wide latitude to ensure that the new aflatoxin policy is implemented in a prudent manner. "Implementation... can be achieved through state control plans, FDA or state agreements with food/feed trade associations or individual companies, or any other mechanism an FDA regional/district office believes will ensure that corn in interstate commerce will not be adulterated" in violation of the Food, Drug and Cosmetic Act, the FDA policy states.

## FDA's Blending Policy

FDA also has announced its intention to allow blending of 1988-crop corn containing aflatoxin with noncontaminated corn under certain very rigid conditions, provided the resulting mixture is used for animal feed only. FDA states that under no conditions will corn containing aflatoxin that is blended with uncontaminated corn be allowed to be used as human food, regardless of the level of aflatoxin present in the resulting mixture.

FDA's policy stipulates the following conditions before blending of corn containing aflatoxin with uncontaminated corn will be allowed:

- A "technically feasible" blending plan must be reviewed and found acceptable by the FDA regional office before blending begins. FDA states the blending plan "should provide assurance" that blending operations "can reasonably be expected to result in a finished lot of corn containing not more than 20, 100, 200 or 300 p.p.b. of aflatoxin depending upon the class of food-producing animal for which the blended corn is intended." Further, FDA's policy states that

the blending "should be accomplished under federal or state supervision, and the finished lot should be approved by federal or state authorities" before being shipped in interstate commerce. "It should be demonstrated to the satisfaction of the supervising federal or state authority that the aflatoxin level of the blended lot is not above the intended level," FDA's policy states.

- FDA officials told the NGFA that while it will be up to the regional and state supervising authorities to determine how to supervise the blending operations, it is FDA's intent that a government official be on-site during the time that the blending occurs. Likewise, FDA will vest in its regional offices the decision on how to ensure the aflatoxin level present in the resulting blended lot is "not above the intended level." Presumably, FDA says, official samples to check the level of aflatoxin present may be required.

- Concerning their plans to implement FDA's blending policy, several FDA regional offices having jurisdiction in the major Corn Belt states told the NGFA that they plan to require preapproval of the blending plan and then will work with state agencies to spot check elevators during blending operations. According to those regional FDA officials contacted by the NGFA, shipments from elevators bending corn under FDA's guidelines also will be spot checked to determine whether the shipped product exceeds the FDA aflatoxin levels for the livestock classes to which it is intended.

- The corn containing aflatoxin that is to be used for blending cannot be shipped in interstate commerce before an FDA office reviews and approves the blending plan. As the rationale for this requirement, FDA's policy states: "If the corn could be shipped in interstate commerce before FDA reviewed the blending plan and found it acceptable, there would be an unavoidable risk that some persons might ship contaminated corn in interstate commerce and blend only if the contaminated shipments were detected by federal or state authorities."

- The blended corn, even if it contains less than 20 p.p.b. of aflatoxin, is not to be used for human food. However, blended corn with less than 20 p.p.b. can be fed to "all animals." The NGFA confirmed today with FDA officials that this includes dairy cattle. Shipments of corn blended to reduce the aflatoxin content to levels of between 100 and 300 p.p.b. can be fed only to those animal species and classes for which they are approved, FDA's policy states.

FDA always has retained administrative latitude to permit blending of corn containing aflatoxin under conditions prescribed by the agency. But in the past the industry has not sought FDA approval to utilize this policy to any substantive degree.

## Documenting Interstate Shipments

FDA's policy is silent on what will constitute valid documentation permitting unencumbered interstate shipments of corn containing aflatoxin within the agency's approved parameters.

FDA officials told the NGFA that regional and district FDA offices having jurisdiction over the geographic location of the company shipping corn containing more than 20 p.p.b. will be responsible for determining the type of documentation required. However, FDA officials said they believe it would be sufficient if bills of lading, bills of sale and other documents that accompany the interstate shipment clearly state that the corn contains an actual or specified range of aflatoxin (i.e., 100 to 200 p.p.b.) and is restricted for use only for the class or classes of livestock and poultry specified in FDA's policy.

In discussions with several FDA regional office directors, the NGFA found most believed that bills of lading, invoices, or other sales documents accompanying the shipment would be sufficient.

Importantly, firms that identity-preserve corn containing various levels of aflatoxin and do not blend it with uncontaminated corn will **not** be subject to the blending requirements of the FDA policy. Of course, any interstate shipments of corn containing aflatoxin -- whether derived from blending or not -- will be subject to FDA jurisdiction.

It is advisable that firms considering whether to utilize FDA's blending policy contact the appropriate regional FDA office in advance to work out the details that will apply.

## Export Shipments

FDA's policy reiterates the exemption for interstate shipments of corn containing aflatoxin destined for export, a provision contained in Section 801(d) of the Food, Drug and Cosmetic Act.

That section of the law states that interstate shipments of corn exceeding FDA's enforcement policy are permitted so long as they:

- are in accordance with the specifications of the foreign buyer;
- do not conflict with the laws of the country to which they are intended for export;
- are "labeled on the outside of the shipping package that it is intended for export; " and
- are not diverted for sale in domestic commerce. FDA's policy notes that "export is not available as a means of salvaging corn in domestic commerce."

FDA says that, as in the past, the "labeling" provision contained in the Food, Drug and Cosmetic Act can be complied with by having bills of lading, invoices and other sales documents accompanying the shipment clearly designate that the corn is destined for export and will not be diverted into domestic commerce

### Ammoniation

FDA's policy states that the agency has "not yet come to a final conclusion" on whether to permit the use of ammoniation to detoxify corn or other feedstuffs containing aflatoxin. "Thus, ammoniation should not be used on aflatoxin contaminated corn or other feedstuffs that may be shipped into interstate commerce, FDA's policy memorandum states.

### Industrial or Nonfood or Nonfeed Uses

Corn found to contain aflatoxin at levels exceeding the policy guidelines, "cannot legally be used for any food or feeding purpose," the FDA policy states. However, FDA's policy does note that the agency will permit interstate shipment of corn containing aflatoxin at levels exceeding those approved for food or feed if it is destined for an industrial, or nonfood or nonfeed use.

Two "possible options" specifically cited for such high aflatoxin corn in the FDA memorandum are:

- **As a component of fertilizer.**
- **In ethanol or gasohol production.** But FDA states that the remaining mash -- a byproduct of the ethanol manufacturing process -- that contains aflatoxin at levels exceeding the FDA recommended guidelines "may not be used for feed purposes."

However, many industrial corn processors reject loads containing even low levels of aflatoxin. The reason: the ethanol production process tends to concentrate the level of aflatoxin present in one of the principal revenue-generating byproducts of the ethanol manufacturing process -- the distillers dried grains -- making them unusable for feed.

### FDA Aflatoxin Policy

FDA's newly issued "Aflatoxin Regulation Policy for Food and Feed" states that the agency can support enforcement action against interstate shipments of corn exceeding the following levels of aflatoxin:

| If corn destined for use for.... | Then FDA can support enforcement action at levels... |
|---|---|
| Human food<br>Feed for immature livestock and poultry<br>Feed for dairy animals<br>Destination unknown | Exceeding 20 p.p.b. |
| Breeding cattle<br>Breeding swine<br>Mature poultry | Exceeding 100 p.p.b. |
| Finishing swine (weighing 100 pounds or more) | Exceeding 200 p.p.b. |
| Finishing beef cattle | Exceeding 300 p.p.b. |

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date OCT - 4 1988

From Associate Commissioner of Regulatory Affairs, (HFC-1)

Subject Regulation of Aflatoxins in Food and Feed

To Regional Food and Drug Directors and District Directors

As a result of this year's severe drought and late rainfalls, the 1988 corn crop may contain higher than normal levels of the mold-produced toxins, aflatoxins. Because of this increase in potential for contaminantion, the agency is being asked by State and industry officials about the status of aflatoxin action levels, the possibility of regulatory relief (e.g. blending, ammoniation), and in general terms how FDA intends to deal with the situation. This memorandum reviews agency policy regarding the regulation of aflatoxin-contaminated corn for food and feed use in order to assure a common understanding of the statutory basis for regulating such commodities and to provide a basis for consistent guidance to FDA field offices and to the affected States and industry.

CNI v. Young

As FDA stated in the Federal Register of February 19, 1988 (53 FR 5043):

> On May 15, 1987, the D.C. Circuit held that FDA action levels are legislative rules rather than general statements of policy within the meaning of the APA (5 U.S.C. 551(5)) and, therefore, must be promulgated in accordance with the notice and comment procedures of that statute. CNI v. Young, 818 F.2d 943 (D.C. Cir. 1987). Because FDA's action levels were issued without such procedures, the court found the action levels to be "invalid." Id. at 950.

FDA issued the FR notice in response to the circuit court's decision and to publicly state that action levels for added poisonous or deleterious substances are not binding on the courts, the public (including industry), or FDA (including agency employees). Thus, when FDA encounters such an added substance in a food or feed, it can decide to take or not to take regulatory action on the finding, whether the level is above or below the action level. Nonetheless, and as stated in my note of May 5, 1988, to regional directors, "current action levels still represent the best guidance available on the levels of chemical and other contaminants the agency would normally consider to be of regulatory interest." Thus, in the case of aflatoxins, this statement directed FDA field offices to continue to use action levels as guidance for assessing whether regulatory actions are likely to be supported.

Regulation of Aflatoxins

Action Levels: Aflatoxins are added poisonous or deleterious substances which, depending upon their level in food or feed, may make food or feed adulterated under section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (FFDCA). This section states that a food (or feed) is deemed to be adulterated if it contains such a substance "which may render [the food (or feed)] injurious to health," and it is the government that must show that there is a reasonable possibility of harm. Thus, the action levels for aflatoxins were intended to represent the levels of contamination at which, in the agency's view, the government could satisfy the "may be injurious" test.

Specifically the agency believed and continues to believe that levels of aflatoxins in excess of 20 parts per billion (ppb) for foods for human consumption, e.g., corn, that are directly susceptible to aflatoxin contamination may render the food commodities injurious to human health. The situation with the action level for aflatoxins in corn as a feedstuff is more complex. In 1980 and 1983, because of severe aflatoxin contamination of the corn crop, FDA allowed the interstate shipment of feed corn containing up to 100 ppb aflatoxins provided the agency was assured that the corn was fed only to mature beef cattle, swine, and poultry. Such assurance was provided by FDA-approved control plans developed and carried out by cooperating state agencies. The 100 ppb limit for aflatoxins in feed corn was based on available scientific evidence and expert witnesses to substantiate that a charge of adulteration under section 402(a)(1) could be supported when corn containing less than 100 ppb aflatoxins intended for mature beef cattle, swine, or poultry.

More recently, the Center for Veterinary Medicine (CVM) has been able to further define subgroups within the mature beef cattle and swine class for which levels of aflatoxins higher than 100 ppb may be necessary to support a "may be injurious to health" charge of adulteration under section 402(a)(1) of the FFDCA. Thus, for finishing swine (e.g., about 100 lbs or greater) aflatoxin levels in excess of 200 ppb could support the charge, while levels above 300 ppb aflatoxins in corn could support a 402(a)(1) charge when the corn is intended for finishing (i.e., feedlot) beef cattle. For breeding beef cattle, breeding swine, and mature poultry, corn containing aflatoxins in excess of 100 ppb aflatoxins could support the adulteration charge.

Recent research has served to better define and confirm that aflatoxin levels of approximately 20 ppb in a dairy fed can result in aflatoxin residues in milk approaching 0.5 ppb. This was and continues to be the reason FDA's 20 ppb action level for feed corn for dairy cattle has not changed. Further, the agency is not aware of any new evidence available that would warrant an immediate change in the 0.5 ppb action level for aflatoxin residues in milk.

For FDA's enforcement activities, and in advising and working with the States and industry on aflatoxin-corn regulatory issues, it is important that FDA's regulatory strategy for aflatoxins be understood. As stated previously the strategy is premised on the fact that FDA must be able to show that any finding of aflatoxins that we decide warrants enforcement action can support a "may be injurious to health" charge.

Accordingly, CVM and the Center for Food Safety and Applied Nutrtion (CFSAN) are confident that enforcement action can be supported in cases involving aflatoxin-contaminated corn shipped in interstate commerce when:

1. Corn containing in excess of 20 ppb aflatoxins is destined for food use by humans, for feed use by immature animals (including immature poultry) and by dairy animals, or its destination is not known.

2. Corn containing in excess of 100 ppb aflatoxins is destined for breeding cattle, breeding swine, or mature poultry.

3. Corn containing in excess of 200 ppb aflatoxins is destined for finishing swine (e.g., 100 lbs or greater).

4. Corn containing in excess of 300 ppb aflatoxins is destined for finishing (i.e., feedlot) beef cattle.

CFSAN is also confident that regulatory action can be supported against milk or milk products being sold in interstate commerce and that contain at least 0.5 ppb aflatoxin residue. FDA expects enforcement actions for milk which exceeds 0.5 ppb to be dealth with under the Interstate Milk Shippers Program. When such levels are encountered following investigation into the feed source of the aflatoxin is indicated.

All these action levels must be viewed and used as guidance rather than definitive, "bright line" standards. Thus, there may be situations where circumstances warrant consideration of enforcement action at below an action level or enforcement action is not pursued when an action level is exceeded.

In considering enforcement action for aflatoxin levels below an action level, the districts must take into account the agency's ability to support the adulteration charge that will be included in the complaint. If a district believes that enforcement action is warranted at levels below an action level, then the recommendation to the appropriate Center should include all compelling reasons for pursuing such action.

Implementation of the above regulatory position can be achieved through State control plans, FDA or State agreements with food/feed trade associations or individual companies, or any other mechanism an FDA regional/district office believes will ensure that corn in interstate commerce will not be adulterated within the meaning of section 402(a)(1).

Blending Policy: In order to deal with the possibly higher than normal aflatoxin level in the 1988 corn crop, we plan to exercise our enforcement discretion to refrain from objecting to the blending of aflatoxin adulterated corn with non-adulterated corn to produce a blended mixture of corn below the above listed action levels for animal feed usage only. This policy only applies to corn from the 1988 crop and for FDA not to object to such blending, all the following conditions should be met:

1. A technically feasible plan for blending has been reviewed and found acceptable by the FDA Regional Office before blending operations begin. It should provide assurance that blending conducted in accordance with the plan can reasonably be expected to result in a finished lot of corn containing not more than 20, 100, 200 or 300 ppb of aflatoxins depending upon the class of food-producing animals for which the blended corn is intended. The blending should be accomplished under Federal or State supervision, and the finished lot should be approved by Federal or State authorities before shipment in interstate commerce. It should be demonstrated to the satisfaction of the supervising Federal or State authority that the aflatoxin level of the blended lot is not above the intended level.

2. The aflatoxin-contaminated corn has not been shipped in interstate commerce before FDA reviewed the blending plan and found it acceptable. (If the corn could be shipped in interstate commerce before FDA reviewed the blending plan and found it acceptable, there would be an unacceptable risk that some persons might ship contaminated corn in interstate commerce and blend only if the contaminated shipments were detected by Federal or State authorities).

3. The blended corn containing less than 20 ppb aflatoxins is for use as feed for all animals but not for human food use. The blended corn containing less than 100 ppb aflatoxins is for use as feed for only breeding beef cattle, breeding swine, and mature poultry. The blended corn containing less than 200 ppb aflatoxins is for use as feed for only finishing beef cattle or finishing swine. The blended corn containing less than 300 ppb aflatoxins is food use as feed for only finishing beef cattle.

Ammoniation: The agency has not as yet come to a final conclusion to allow the use of ammoniation to detoxify aflatoxin-contaminated corn or other feedstuffs. Thus, ammoniation should not be used on aflatoxin - contaminated corn or other feedstuffs that may be shipped into interstate commerce.

Export: Corn that contains aflatoxins and that is adulterated within the meaning of section 402(a)(1) may be exported provided it was originally intended for export and all the other conditions of section 801(d)(1) are met. In accord with section 801(d)(1)(D), export is not available as a means of salvaging corn in domestic commerce that has been found to be in violation of section 402(a)(1).

Disposal of Adulterated Corn: Corn found to be in violation of section 402(a)(1) cannot be legally used for any food or feeding purposes domestically. It may, therefore, become necessary for States or industry to find acceptable means of disposing of such lots. Possible options include:

- Using the corn as a component of fertilizer.

- Ethanol or gasahol production - the remaining mash containing aflatoxins in excess of the above action levels may not be used for feed purposes.

Any questions on any of the above policies should be directed to John Wessel or Cathy Carnevale, Contaminants Policy Staff (HFC-6) at FTS 443-1815.

John M. Taylor

Attachment 1
FGIS PROGRAM DIRECTIVE 906.2
4-9-86

MEMORANDUM OF UNDERSTANDING

Between The

FEDERAL GRAIN INSPECTION SERVICE
U.S. DEPARTMENT OF AGRICULTURE

And The

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

## I. PURPOSE

This agreement sets forth the working arrangements between the Federal Grain Inspection Service (FGIS) and the Food and Drug Administration (FDA) regarding their respective responsibilities in the inspection and standardization of grain, rice, pulses, and food products.*

## II. BACKGROUND

This Memorandum of Understanding revises and replaces the Memorandum of Agreement on this subject which went into effect on April 15, 1980.

## III. STATUTES RELATING TO THE AGREEMENT

A. The Food and Drug Administration of the Department of Health and Human Services enforces the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) (the act). In fulfilling its responsibilities under the act, FDA insures that foods, including animal feed, are safe and wholesome and are labeled in a truthful, nonmisleading manner. FDA accomplishes this in part, by inspecting facilities that process, hold, and distribute grain, rice, pulses, and similar food. FDA also examines samples of inspected food to determine whether the food is adulterated or misbranded within the meaning of the act. FDA also promulgates, under the act, standards of identity, quality, and fill of container for food products.

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*This agreement applies only to those commodities assigned to FGIS by the Secretary of Agriculture.

B. The Federal Grain Inspection Service of the U.S. Department of Agriculture under the authority of (1) the U.S. Grain Standards Act (7 U.S.C. 71 et seq.) and the regulations thereunder (7 CFR Part 800 through 810), and (2) the Agricultural Marketing Act of 1946 (7 U.S.C. 1621 et seq.) and the regulations thereunder (7 CFR Part 68), performs voluntary and mandatory inspection and weighing services designed to aid in the efficient marketing of agricultural products. These services include developing specifications and standards; furnishing inspection, grading, and weighing services; and issuing certificates of quantity, quality, and condition to producers, processors, shippers, buyers, and other interested parties. An FGIS certificate provides reliable commercial information concerning the quantity, quality, and condition of agricultural products.

## IV. SUBSTANCE OF AGREEMENT

A. When performing functions under the act that relate to agricultural products, persons, and facilities that are also subject to the laws and regulations administered by FGIS, FDA will:

1. During FDA inspection of a facility that processes, packs, or holds agricultural products, request the FGIS inspector or FGIS licensee stationed at a facility, to accompany the FDA inspector during the inspection. The FDA inspector will discuss with the FGIS inspector or FGIS licensee any conditions that the FDA inspector believes may result in violations of the act.

2. Request FGIS to furnish information concerning quality determinations of specific lots of products against which FDA has taken or may take action. When involved in such an action FDA will consider the results of official FGIS inspection certificates and other available data provided the information is relevant to the current condition of the product and the nature of the violation charged.

When an FDA action is to be based on an analysis by FGIS or an FGIS licensee and FDA has not received the results of an appeal analysis, FDA through its appropriate field office will contact the designated FGIS field liaison person (see IV.B.4.), confirm that an appeal analysis is being conducted, and request an oral report of the results of the analysis as soon as possible.

3. Notify FGIS concerning details of objectionable conditions found by FDA to exist in processing plants, packing plants, grain elevators, or any other facilities where FGIS provides official services.

4. Notify FGIS of the criteria FDA uses to determine whether FDA should consider an action under the act against an agricultural product. Notification will ensure that FGIS does not classify an objectionable commodity as acceptable.

5. Upon request of FGIS, review for possible conflict with the misbranding provisions of the act the following: labels, legends, stamps, and other marks on products that are packed under the various official services.

B. When performing functions under the laws and regulations administered by FGIS that relate to agricultural products, persons, and facilities that are also subject to the act, FGIS will:

1. Promptly notify FDA of the facilities that are subject to withdrawal or suspension of service, termination of contract, or denial of official FGIS services because of insanitary conditions or other processing deficiencies.

2. Investigate any report from FDA that a processor, packer, merchandiser, or facility operator using official FGIS services has not corrected objectionable conditions found by FDA. Upon completion of this investigation, FGIS will initiate appropriate action and notify FDA of the action taken.

3. Refuse to inspect products which have been seized by FDA or which are known to be involved in formal FDA actions. This does not preclude official reinspection of authorized samples if the FDA action involves products which have been officially inspected.

4. Promptly report to FDA the results of any inspection or analysis (including results of any appeal analysis, when available) for any product that may be actionable under the act. Such report shall include information to assist in locating and identifying the product and the name of an appropriate field liaison person in FGIS.

5. Furnish FDA, upon request, any pertinent information concerning the grade or quality of FGIS inspected specific lots of products, against which FDA has taken or may take action.

C. It is mutually agreed that:

1. Field liaison will be maintained between FDA District offices and FGIS designated field liaison persons as indicated in IV.B.4. General matters involving this agreement may be referred to the agencies' liaison officers as indicated in VI.A. and VI.B.

2. Proposed regulations initiated by either agency which affect, establish, or amend food standards or other products covered by this agreement will be referred to the other agency for review and comment before the proposed regulations are published for broader comment.

3. Both agencies will cooperate with industries in improving sanitation and food handling practices in processing plants, packing plants, or other facilities.

4. Both agencies will exchange data and cooperate in developing sampling plans, methodology, and guidelines for determining natural and unavoidable defects common to products officially inspected.

## V. NAME AND ADDRESS OF PARTICIPATING AGENCIES

A. Federal Grain Inspection Service,
U.S. Department of Agriculture,
14th St. and Independence Ave.,
Washington, DC 20250.

B. Food and Drug Administration,
5600 Fishers Lane,
Rockville, MD 20857.

## VI. LIAISON OFFICERS

A. For the Food and Drug Administration:

Director, Office of Compliance,
(currently, ~~John M. Taylor~~),
Center for Food Safety and Applied Nutrition (HFF-300),
200 C St. SW.,
Washington, DC 20204,
202-485-0160.

B. For the Federal Grain Inspection Service:

Director, Field Management Division,
(currently, John W. Marshall),
Federal Grain Inspection Service,
14th St. and Independence Ave.,
Washington, DC 20250,
202-382-0228.

## VII. PERIOD OF AGREEMENT

This agreement, when accepted by both parties, will be effective indefinitely. It may be modified by mutual consent or terminated by either party upon a 30-day written notice.

APPROVED AND ACCEPTED FOR THE FEDERAL GRAIN INSPECTION SERVICE

BY: K. A. Gilles

TITLE: Administrator
Federal Grain Inspection Service

DATE: October 9, 1985

APPROVED AND ACCEPTED FOR THE FOOD AND DRUG ADMINISTRATION

BY: Joseph P. Hile

TITLE: Associate Commissioner
for Regulatory Affairs

DATE: NOV - 8 1985

Attachment 2
FGIS PROGRAM DIRECTIVE 906.2
3-18-87

## FDA DISTRICT OFFICIALS

### Atlanta

| | |
|---|---|
| DIB-Roger E. Kline | (404) 347-3151<br>FTS 257-3151 |
| DCB-Lamar Furr | (404) 347-3162<br>FTS 257-3162 |
| DD-John H. Turner | (404) 347-4344<br>FTS 257-4344 |

### Baltimore

| | |
|---|---|
| DIB-Janice F. Oliver | (301) 962-4099<br>FTS 922-4099 |
| DCB-J. Donald Sherry | (301) 962-4040<br>FTS 922-4040 |
| DD-Thomas L. Hooker | (301) 962-4012<br>FTS 922-4012 |

### Boston

| | |
|---|---|
| DIB-Donald J. Johnson | (617) 223-2266<br>FTS 223-2266 |
| DCB-John A. Hamilton | (617) 565-4724<br>FTS 835-4724 |
| DD-(Vacant) | (617) 565-4711<br>FTS 835-4711 |

### Buffalo

| | |
|---|---|
| DIB-Robert L. Hart | (716) 846-4467<br>FTS 437-4467 |
| DCB-Edward W. Thomas | (716) 846-4484<br>FTS 437-4484 |
| DD-E. Pitt Smith | (716) 846-4478<br>FTS 437-4478 |

### Chicago

| | |
|---|---|
| DIB-George A. Masters | (312) 353-7769<br>FTS 353-7769 |
| DCB-Larry E. Ormsbee | (312) 353-9752<br>FTS 353-7382 |
| DD-(Vacant) | (312) 353-7379<br>FTS 353-7379 |

### Cincinnati

| | |
|---|---|
| DIB-James R. Dupre | (513) 684-3505<br>FTS 684-3505 |
| DCB-Henry L. Fielden | (513) 684-3501<br>FTS 684-3501 |
| DD-James C. Simmons | (513) 684-3504<br>FTS 684-3504 |

### Dallas

| | |
|---|---|
| DIB-Theodore L. Rotto | (214) 767-0312<br>FTS 729-0312 |
| DCB-Robert J. Hatfield | (214) 767-0319<br>FTS 729-0319 |
| DD-Gerald E. Vince | (214) 767-0317<br>FTS 729-0317 |

### Denver

| | |
|---|---|
| DIB-Edward R. Esparza | (303) 844-4915<br>FTS 564-4915 |
| DCB-Douglas C. Payne | (303) 844-4915<br>FTS 564-4915 |
| DD-Leroy M. Gomez | (303) 844-4915<br>FTS 564-4915 |

### Detroit

| | |
|---|---|
| DIB-Eugene S. Spivak | (313) 226-2253<br>FTS 226-2253 |
| DCB-John P. Dempster | (313) 226-7847<br>FTS 226-7847 |
| DD-Alan L. Hoeting | (313) 226-6260<br>FTS 226-6260 |

### Kansas City

| | |
|---|---|
| DIB-Mary H. Woleske | (816) 374-5623<br>FTS 758-5623 |
| DCB-(Vacant) | (816) 374-5521<br>FTS 758-5521 |
| DD-James A. Adamson | (816) 374-5521<br>FTS 758-5521 |

Attachment 2
FCIS PROGRAM DIRECTIVE 906.2
3-18-87

Los Angeles

| | | |
|---|---|---|
| DIB-Roger L. Lowell | (213) | 252-7588 |
| | FTS | 983-7588 |
| DCB-Thomas L. Sawyer | (213) | 252-7612 |
| | FTS | 983-7612 |
| DD-George J. Gerstenberg | (213) | 252-7856 |
| | FTS | 983-7856 |

Minneapolis

| | | |
|---|---|---|
| DIB-John H. Scharmann | (612) | 349-3920 |
| | FTS | 787-3920 |
| DCB-Edwin S. Dee | (612) | 349-3914 |
| | FTS | 787-3914 |
| DD-John Feldman | (612) | 349-3904 |
| | FTS | 787-3904 |

Nashville

| | | |
|---|---|---|
| DIB-Patrick J. Pouzar | (615) | 736-5851 |
| | FTS | 852-5851 |
| DCB-Robert C. Fish | (615) | 736-7127 |
| | FTS | 852-7127 |
| DD-Hayward E. Mayfield | (615) | 736-7222 |
| | FTS | 852-7222 |

Newark

| | | |
|---|---|---|
| DIB-Edward H. Wilkens | (201) | 645-6230 |
| | FTS | 341-6230 |
| DCB-Anthony Panzica | (201) | 645-2177 |
| | FTS | 341-2177 |
| DD-Matthew H. Lewis | (201) | 645-3023 |
| | FTS | 341-3023 |

New Orleans

| | | |
|---|---|---|
| DIB-Doyle E. Smith | (504) | 589-6344 |
| | FTS | 682-6344 |
| DCB-James R. McClellan | (504) | 589-2403 |
| | FTS | 682-2403 |
| DD-Robert O. Bartz | (504) | 589-2401 |
| | FTS | 682-2401 |

New York

| | | |
|---|---|---|
| DIB-Jerome G. Woyshner | (718) | 965-5709 |
| | FTS | 663-5709 |
| DCB-Clarence Waltrous | (718) | 965-5707 |
| | FTS | 663-5707 |
| DD-Joseph J. Faline | (718) | 965-5301 |
| | FTS | 663-5301 |

Orlando

| | | |
|---|---|---|
| DIB-Carl C. Reynolds | (305) | 855-0900 |
| | FTS | 821-7160 |
| DCB-Edward R. Atkins | (305) | 855-0900 |
| | FTS | 821-7160 |
| DD-Douglas D. Tolen | (305) | 855-0900 |
| | FTS | 821-7160 |

Philadelphia

| | | |
|---|---|---|
| DIB-Paula J. Oliver | (215) | 597-4393 |
| | FTS | 597-4393 |
| DCB-Philip Sheeler | (215) | 597-3040 |
| | FTS | 597-3040 |
| DD-Loren Y. Johnson | (215) | 597-3708 |
| | FTS | 597-3708 |

St. Louis

| | | |
|---|---|---|
| DIB-Charlie Bringman | (314) | 425-4137 |
| | FTS | 279-4137 |
| DCB-Spencer Sorenson | (314) | 425-5026 |
| | FTS | 279-5026 |
| DD-Raymond K. Hedblad | (314) | 425-4137 |
| | FTS | 279-4137 |

San Francisco

| | | |
|---|---|---|
| DIB-Wayne A. Mazanec | (415) | 556-1456 |
| | FTS | 556-1456 |
| DCB-Steven G. Kendall | (415) | 556-0780 |
| | FTS | 556-0780 |
| DD-Ronald M. Johnson | (415) | 556-0318 |
| | FTS | 556-0318 |



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San Juan

| | |
|---|---|
| DIB-David K. Haggard | (809) 753-4495 |
| DCB-Nancy C. Acevedo | (809) 753-4931 |
| DD-Lynn A. Campbell | (809) 753-4245 |

Seattle

| | |
|---|---|
| DIB-James A. Davis | (206) 442-5319<br>FTS 399-5319 |
| DCB-Raymond V. Mlecko | (206) 442-5310<br>FTS 399-5310 |
| DD-(Vacant) | (206) 442-5304<br>FTS 399-5304 |

Attachment 3
FGIS PROGRAM DIRECTIVE 906.2
4-9-96

**WRITTEN REPORT FORMAT**

SUBJECT: Confirmation of Telephone Report

TO: Food and Drug Administration
District Office

This will confirm our telephone report of (date) regarding the following inferior lot of (product).

| Item | | Remarks |
|---|---|---|
| Commodity | : | |
| Contract No. | : | |
| Carrier Identification | : | |
| Lot No. | : | |
| Sampling Date | : | |
| Plant/Elevator | : | |
| Location | : | |
| Amount | : | |
| Destination | : | |
| Actionable Conditions | : | |

Field Office Manager/Agency Manager
Field Office/Agency

cc: Area Program Chief/Field Office

U.S. Government Printing Office : 1986 - 490-918/40206

United States Department of Agriculture
Federal Grain Inspection Service

# Program Directive 906.2 4-9-86

IMPLEMENTATION OF THE FGIS-FDA MEMORANDUM OF UNDERSTANDING

I. PURPOSE

This Instruction transmits a copy of the "Memorandum of Understanding Between the Federal Grain Inspection Service of the United States Department of Agriculture and the Food and Drug Administration of the Department of Health and Human Services Concerning the Inspection of Grain, Rice, Pulses, and Food Products" and establishes procedures for implementing the requirements of the Understanding. See AMS/FGIS Instruction 101-3, "Listing of Agricultural and Food Commodities Assigned AMS and FGIS for Program Purposes," for the list of commodities assigned to the Federal Grain Inspection Service (FGIS).

II. REPLACEMENT HIGHLIGHTS

This Program Directive replaces FGIS Instruction 906-2 with pages dated 7/13/80, 2/24/81, and 9/12/83. Section V, G, "Other Defects," was incorporated for additives not approved by the Food and Drug Administration (FDA).

III. BACKGROUND

FGIS and FDA have certain mutual objectives in carrying out their respective service and regulatory functions. Therefore, after consultation with FDA, FGIS has revised the criteria for reporting contaminated lots of grain, rice, pulses, and processed food products to FDA. The new criteria will assure the most effective implementation of the responsibilities of the two Agencies and will be responsive to the need for protection of the public from contaminated commodities.

IV. DEFECT ACTION LEVELS

In accordance with the FGIS-FDA Memorandum of Understanding (attachment 1), FGIS shall report to FDA any lots of grain, rice, pulses, or food products which are considered to be actionable under the Federal Food, Drug, and Cosmetic Act. Submitted samples that exceed the actionable level shall not be reported.

Lots are actionable if they contain animal or insect filth, toxic substances, objectionable odor, deleterious foreign matter, nonapproved FDA additives, or distinctly low quality matter at or above the defect action level (DAL). The DAL's for graded commodities and nongraded commodities are listed in sections IV and V, respectively.

V. DEFECT ACTION LEVELS FOR GRADED COMMODITIES

A. Animal Filth in Wheat, Rye, Rice, and Pulses.

1. Bird droppings: 2 or more droppings per 1,000 grams.

2. Rodent pellets: 2 or more pellets per 1,000 grams or 9 mg/kg.

3. A combination of filth types: 1 or more bird droppings and 1 or more rodent pellets per 1,000 grams.

B. Toxic Substances in Grain, Rice, and Pulses.

1. Castor beans: 2 or more per 1,000 grams.

2. Crotalaria seeds: 3 or more per 1,000 grams.

3. Treated seeds, such as pink kernels or mercury-treated kernels.

a. Rice and pulses: 4 or more per 1,000 grams.

b. Grain: 20 or more per 1,000 grams.

4. Aflatoxin in corn: More than 20 ppb.

C. Objectionable Odor in Grain, Rice, and Pulses. A commercially objectionable foreign odor.

D. Deleterious Foreign Matter.

1. In grain:

a. Metal fragments: 2 or more in the lot as a whole or in the original sample.

b. Glass fragments: 2 or more in the lot as a whole or in the original sample.

2. In rice and pulses:

a. Metal fragments: 1 or more in the lot as a whole or in the original sample.

b. Glass fragments: 1 or more in the lot as a whole or in the original sample.

c. Stones:

(1) All rice except rough rice: More than 0.1 percent, by weight.

(2) Pulses: More than 0.3 percent, by weight.



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E. Insects and Insect Filth in Rice and Pulses. A determination of U.S. Sample grade or of meeting the requirements for U.S. Sample grade on account of live or dead insects, insect webbing, or insect refuse.

F. Distinctly Low Quality (Grain and Rice). A determination of the special grade Distinctly Low Quality (DLQ).

G. Other Defects. The application of any additive not approved by FDA. If there is a question about an additive, contact the local FDA office for a ruling.

VI. DEFECT ACTION LEVELS FOR NONGRADED COMMODITIES

A. Wheat Flour (All Types), Pasta Products, and Farina.

1. Insect fragments: 50 or more in 50 grams.

2. Whole insects and/or larvae: 2 or more in 50 grams.

3. Rodent hairs: 2 or more in 50 grams.

4. Rodent excreta fragments: 2 or more in 50 grams.

B. Oat Products, Sorghum Products, All Cornmeal and Grits, Soy-Fortified Rice, and Corn Soy Blend.

1. Insect fragments: 50 or more in 50 grams.

2. Whole insects and/or larvae: 2 or more in 50 grams.

3. Rodent hairs: 3 or more in 50 grams.

4. Rodent excreta fragments: 2 or more in 50 grams.

C. Bulgur and Soy-Fortified Bulgur.

1. Insect fragments: 50 or more in 50 grams.

2. Whole insects and/or larvae: 5 or more in 50 grams.

3. Rodent hairs: 3 or more in 50 grams.

4. Rodent excreta fragments: 2 or more in 50 grams.

D. Wheat Soy Blend and Sweetened Wheat Soy Blend.

1. Insect fragments: 50 or more in 50 grams.

2. Whole insects and/or larvae: 5 or more in 50 grams.

3. Rodent hairs: 3 or more in 50 grams.

4. Rodent excreta fragments: 2 or more in 50 grams.

VII. A. Telephone Report. Immediately after ascertaining that REPORTING a lot is actionable (meets or exceeds its DAL), the office ACTIONABLE performing the inspection (agency, cooperator, or field LOTS office) shall report its findings by telephone to the applicant for inspection and to FDA's district office nearest to the location of the actionable lot (see attachment 2). Telephone calls to FDA should only be made collect when FTS is not available. Calls to FDA district offices shall be directed to the following individuals in the indicated preference order.

1. Director, Investigations Branch (DIB)

2. Director, Compliance Branch (DCB)

3. District Director (DD)

B. Written Report. The telephone report shall be confirmed promptly in writing (see attachment 3). Upon request, the work portion of the sample shall be forwarded to FDA using USDA-franked tags. The inspection certificate shall be presented to the applicant for inspection. When the reporting agency is not FGIS, a copy of the certificate and a copy of the written report to FDA shall be forwarded to the appropriate FGIS field office.

VIII. CERTIFICATION All pertinent information shall be included on official certificates issued to the applicant. Upon request by an interested person, inspections on lots of grain are subject to reinspection, appeal inspection, and/or Board appeal inspection in accordance with the United States Grain Standards Act, as amended. Whenever grain lots previously reported by agencies or FGIS as actionable are subsequently requested to be reinspected, appealed, and/or Board appealed by the applicant, the FGIS field office shall report such findings promptly to the applicant and FDA.

Requests for appeal on rice, pulses, and processed commodities are limited to an examination of the file sample and may not be performed on a new sample drawn for appeal purposes when the lot is actionable by FDA. (See § 68.21(g), Part 68 of the regulations under the Agricultural Marketing Act of 1946.)

X. QUESTIONS

Direct questions concerning the Memorandum of Understanding, this Instruction, or the locations of FDA district offices to your Area Program Chief.

John W. Marshall

Director
Field Management Division

UNITED STATES DEPARTMENT OF AGRICULTURE
Federal Grain Inspection Service
Washington, D.C. 20250

FGIS INSTRUCTION 918-38

ACTION BY: Area Program Chiefs, Field Office Managers, and Agency Managers

INFORMATION FOR: Interested Persons in the Grain Industry

# Testing Corn for Aflatoxin

## I. PURPOSE

This Instruction establishes procedures for scanning and testing corn for aflatoxin using (1) longwave ultraviolet light, black light (BL) and (2) the Holaday-Velasco minicolumn (MC) and thin-layer chromatography (TLC) methods. The MC method is capable of detecting aflatoxins in corn at concentrations equal to and greater than 10 parts per billion (ppb). The TLC method is a more complex method; however, it provides more quantitative results. The sampling, certificating, billing, file sample retention, and monitoring procedures are policies established by the Federal Grain Inspection Service (FGIS).

## II. POLICY

The Administrator has determined that FGIS will provide aflatoxin testing services for corn. These services are provided under the authority of the Agricultural Marketing Act of 1946, as amended (AMA), and the 7 CFR Part 68 regulations.

## III. BACKGROUND

Aflatoxin is a chemical substance resulting from the metabolic process of certain molds in grains and other foodstuffs. With current detection techniques, accurate measurement of the level of aflatoxin contamination is possible.

## IV. REQUEST FOR SERVICE

Applicants may request aflatoxin testing as follows:

(IV)

Applicants must submit a completed application to official personnel. Applicants who submit samples directly to a field office or the Commodity Testing Section (CTS) must send a completed application with the samples. Applications must show the test desired.

Applicants may request BL (shiplots only), MC, or TLC testing. They must apply for MC testing to be eligible for both MC and TLC testing services on the same sublot, lot, or submitted sample; that is, if they apply for a TLC test, subsequent MC testing will not be provided.

When a test result is minicolumn positive (MCP), an applicant may request a TLC test as part of the original request. If the applicant does not request a TLC test, a certificate will be issued showing the MC test result. The applicant may appeal this result. If the result is appealed, an appeal MC test will be performed and an appeal certificate issued showing the result. Once a MC appeal has been performed, no further aflatoxin test can be performed on this lot.

A. Services Provided at Export Field Offices

FGIS will only perform onsite aflatoxin scanning and testing in an approved laboratory area. Approved onsite laboratory criteria are provided in exhibit A. When two or more export elevators are in close proximity to each other, an approved laboratory may be consolidated at one location with the consent of each elevator's management. When an approved laboratory area is not provided, services will be available only by sending samples to CTS.

When aflatoxin testing of shiplots is requested, FGIS will perform original aflatoxin BL scanning and original and appeal MC testing services on a sublot-by-sublot basis (see exhibits B-1 and B-2). An applicant may request BL or MC testing of sublots.

1. When BL testing is requested:

a. Each sublot sample is scanned with BL; and

b. Each black light positive (BLP) sublot sample and the black light negative (BLN) ship composite sample will be analyzed by the MC method.

2. When MC testing is requested, each sublot sample is analyzed by the MC method. Ship composite samples are not maintained and tested in this instance.

Onsite MC and TLC services may also be provided on bargelots, carlots, trucklots, and submitted samples.

B. Services Provided at Nonexport Field Offices

Nonexport offices do not provide aflatoxin scanning and MC and TLC testing services. CTS will provide MC and TLC services for nonexport offices.

(IV, B)

1. Submitted Samples (Sample-Inspection) - Applicants may deliver samples to the nearest field office for forwarding to CTS. However, samples should be mailed directly to CTS for faster service.

Applicants who decide to mail samples directly to CTS must send a check with the samples to cover the testing cost. Checks must be made payable to the U.S. Department of Agriculture. Testing costs can be obtained from the nearest field office.

2. Official Samples (Lot-Inspection) - Official personnel will sample the lot and submit a representative 10-pound sample to CTS.

C. Services Provided by the Commodity Testing Section

CTS provides original and appeal MC and TLC services on samples furnished by applicants, nonexport offices, and export offices that do not have approved laboratories. It also provides, upon request, appeal TLC service on samples furnished by export offices that have FGIS-approved TLC laboratories.

CTS' mailing address is:

Commodity Testing Section
USDA, FGIS
Building 306, Room 209
Agricultural Research Center, East
Beltsville, Maryland 20705

V. GENERAL PROCEDURES

Official personnel must complete a "Services Performed Accounting Report," for each shiplot, bargelot, carlot, trucklot, or submitted sample tested. When samples are submitted to a different laboratory for analysis, show the name of the office submitting the sample and the type of test required in the "Number and Kind of Containers" block. The yellow copy of the report must accompany the sample.

A. Sampling

Samples must be obtained according to the guidelines in book I of the Grain Inspection Handbook. A minimum 10-pound (approximately 4,540 grams) sample is required for aflatoxin testing.

B. Portion Sizes (See exhibit C.)

All portions must be cut from the sample using a riffle divider. Exactly 50.0 grams is required for MC and TLC testing. (Adjust to final weight with a spatula or similar device.) All other portion sizes outlined in this instruction are approximate.

VI. PROCEDURES

A. Black Light Scanning (Sublots Only)

1. Grind the entire 10-pound sample using the Viking Hammer Mill fitted with a 1/2-inch screen and collect the ground sample in a new polyethylene bag(s).

2. Spread the entire ground sample on a nonreflective, flat surface in a darkened area and scan it for particles that glow a bright, greenish yellow color.

3. Compare all particles that glow a bright, greenish yellow color to the BL standard.

4. A sublot is considered BLN when the sample does not contain any particles that glow a bright, greenish yellow color. When a sublot sample is considered BLN:

a. Mix the coarsely ground 10-pound sample by running it through a riffle divider three times.

b. After mixing, cut out a 2.5-pound (approximately 1,135 grams) portion.

c. Grind the entire 2.5-pound portion using the Viking Hammer Mill fitted with a 1/32-inch screen.

d. Place the 2.5-pound portion in a new polyethylene bag and mix it thoroughly by repeatedly inverting and shaking the closed bag for at least 1 minute.

e. Cut out a 500-gram file sample and a portion for the ship composite sample. Portions for the ship composite sample must be obtained in equal amounts from each BLN sublot so that a minimum of 1,000 grams is obtained for the entire ship.

5. A sublot is considered BLP when the sample contains one or more particles that glow a bright, greenish yellow color. When sublot samples are considered BLP, they must be tested by the MC method as prescribed in VI B.

B. MC and TLC Testing

When the BLN ship composite sample is being tested, proceed to step 6.

1. If the 10-pound sample has not been previously ground, grind the entire 10-pound (approximately 4,540 grams) sample using the Viking Hammer Mill fitted with a 1/2-inch screen and place it in a new polyethylene bag.

2. Once the 10-pound sample has been coarsely ground, mix it by running it through a riffle divider three times.

3. After mixing, cut out 2.5 pounds (approximately 1,135 grams).

4. Grind the entire 2.5-pound portion using a Viking Hammer Mill fitted with a 1/32-inch screen.

5. Place the 2.5-pound portion in a new polyethylene bag and mix it thoroughly by repeatedly inverting and shaking the closed bag for at least 1 minute.

6. Cut out a 500-gram work (MC test) sample and a 500-gram file sample.

7. Cut out exactly 50.0 grams from the 500-gram work (MC test) sample. Retain the balance of the work sample until the test has been completed.

8. Perform the MC test and, if requested, the TLC test according to sections 26.020 through 26.025 for MC or 26.031 through 26.049 for TLC of the Official Methods of Analysis of the Association of Official Analytical Chemist, Thirteenth Edition, 1980 (see exhibit D (MC)).

A lot or sublot is considered aflatoxin negative when the sample contains 20 ppb or less of aflatoxin.

When a sample tests MCP and the applicant requests TLC as part of the original request, cut out exactly 50.0 grams from the balance of the work (MC test) sample and perform the TLC test.

Portions of sublots that initially test BLP and are determined to be minicolumn negative (MCN) or thin-layer chromatography negative (TLCN) must not be combined with the ship composite sample. However, official personnel must combine these portions with the ship composite sample when applicants, in their applications for aflatoxin testing of shiplots, request TLC testing of ship composite samples.

C. Recording Results

When aflatoxin testing is being performed on shiplots, record the final test (BLN, MCN, MCP, TLCN, TLCP) result for each sublot on the Inspection Log, in one of the blank columns or in the "Remarks" section. For all other lots, including the ship composite, record the results on the Services Performed Accounting Report being completed for that lot.

CTS, and FGIS-approved TLC laboratories who perform aflatoxin testing on samples forwarded by other offices, must record the test results on a "Confirmation of Telephone Conversation" form. A copy of this form must be sent to the office that sent the sample so that it can be attached to the Service Performed Accounting Report being completed for that lot.

D. Reporting Results

CTS and FGIS-approved TLC laboratories will telephone aflatoxin test results to the field office that forwarded the sample. When samples have been forwarded directly to these laboratories by the applicant, the laboratories will notify the applicant by telephone.

Official personnel will report aflatoxin test results to the applicant as soon as practicable after the test has been completed. Report results as follows:

1. Black light as BLN or BLP.

2. Minicolumn as MCN or MCP.

3. Thin-layer chromatography as TLCN or thin-layer chromatography positive (TLCP). When TLC testing has been performed, the actual ppb's will be reported to the applicant when requested.

All sublots, ship composite, and other lots that test aflatoxin positive (more than 20 ppb) must be reported to the Food and Drug Administration (FDA) according to FGIS Instruction 906-2, "Implementation of the FGIS-FDA Memorandum of Understanding," when:

1. The positive test result has not been appealed, and a TLC has not been requested as part of the original request; or

2. The positive test result has been appealed, and the result is positive.

VII. CERTIFICATION RESULTS

CTS will issue and distribute certificates when an applicant has mailed the sample directly to CTS for analysis. In all other cases, the field office that received the request for aflatoxin testing will issue and distribute the certificates.

Aflatoxin test results will be certificated by showing the following statement in the "Results of Inspection" block:

> "The aflatoxin result is (positive or negative). This analysis reflects the aflatoxin level at the time the test was performed and may not reflect the level at a future date."

This statement will be used to report MC and TLC aflatoxin test results regardless of methodology used. In no instance will BL results be certificated. The following statement may also be used, at the applicant's request, when the TLC method is used and the test result is positive.

> "The aflatoxin result using the thin-layer chromatography method is (show parts per billion) parts per billion. This analysis reflects the aflatoxin level at the time the test was performed and may not reflect the level at a future date."

(VII)

A. Lot Inspection (Official Samples)

Use a Commodity Inspection - Lot Inspection certificate to record aflatoxin test results. For shiplots, the entire shiplot may be certificated on one certificate when all sublots, including the ship composite, test negative. However, when one or more sublots test positive, certificate according to the option selected under VIII.

In addition to the required statement, complete the applicable sections of the certificate as follows:

1. In the "Identification" block show the name of the vessel or other type of carrier identification. When a sublot has been removed from the vessel or returned to the elevator from shipping bins, show the vessel name and the sublot number.

2. In the "Quantity" block, show the total amount of corn in the lot or sublot.

3. In the "Remarks" section, show a stowage statement indicating the hold numbers where the corn was loaded when the certificate represents a shiplot inspection. If a sublot has been removed from the vessel or returned from shipping bins, show a statement that the sublot was returned.

B. Sample Inspection (Submitted Samples)

Use a Commodity Inspection - Sample Inspection certificate to record the test results for aflatoxin.

In addition to the required statement, complete the applicable sections of the certificate as follows:

1. In the "Identification of Sample" block, use a code number assigned by the applicant or assign one. The sample cannot be identified on the certificate by descriptive terms which would ordinarily apply to lot inspections such as the name of the carrier, warehouse, or lot quantity.

2. In the "Quantity of Sample" block, record the actual amount of the sample submitted.

C. Divided Original Certificates

Divided original certificates may be issued according to the guidelines in section 8.22 of the Rice Inspection Handbook.

D. Appeal Certificates

For appeal inspections, insert the words "Federal Appeal" at the top of the certificate.

VIII. APPLICANT'S OPTIONS WHEN TEST RESULTS ARE POSITIVE

When a MC test on a sublot, ship composite, other lots, and submitted samples is positive, the applicant has the following options:

A. Request TLC testing as part of the original request, or

B. Request an appeal MC test, or

C. Request a certificate indicating the results are positive, or

D. In the case of shiplots, discharge the sublot(s) according to section X.

If option A is requested and the TLC test is positive, the applicant may request an appeal TLC test or options C and D, as applicable.

Certificate according to section VII and the option selected.

IX. APPEAL INSPECTIONS

New inspections cannot be performed on aflatoxin-positive lots or sublots (7 CFR 68.29). However, any interested party may appeal an aflatoxin test result by submitting an application to the office that performed the original inspection. An appeal inspection will be performed using the same procedure that was used for the original result. Appeal inspections are limited to an analysis of the official file sample (7 CFR 68.21).

Applicants may request that CTS or a specific FGIS-approved TLC laboratory perform appeal inspections using the TLC method. All appeal inspections using the MC method will be performed at the location where the original test was performed.

X. DISCHARGING SUBLOTS

If an applicant for inspection elects to discharge a sublot under section VIII, the quantity contained in the sublot plus a portion equivalent to one-half of the sublot must be removed. The portion that is equivalent to one-half of the sublot must be removed from the stowage space where the sublot was stowed. However, if the sublot was the only sublot loaded into an identified stowage space or was held in shipping bins for grade and aflatoxin analysis, only that sublot need be discharged. There will not be any sampling or testing of the corn remaining in the stowage space after discharge.

XI. RETAINING AND MAINTAINING SAMPLES (See exhibit C.)

Place each sample portion in a separate container. Clearly mark each container so as to identify it from any other sample portion packaged.

Hold domestic and export file sample portions 30 and 60 days, respectively.

(XI)

If a sublot, lot, or submitted sample is MC or TLC positive and the test result has not been appealed or has been appealed and the appeal test result is positive, decontaminate and dispose of all sample portions according to exhibit E.

XII. PROTECTING INDIVIDUALS

FGIS personnel shall abide by the health and safety rules and the medical examinations provided in exhibits E and F, respectively.

XIII. MONITORING BY THE COMMODITY TESTING SECTION WHEN MC OR TLC TESTING IS PERFORMED ONSITE

A. Official personnel shall select, prepare, and submit monitor samples to CTS as follows:

1. Select 1 file sample, biweekly, at random, from every 10 samples scanned by BL or tested by the MC or TLC methods. If fewer than 10 samples are tested in the 2-week period, send a minimum of 1 sample for that period.

2. Prepare a Grain Sample Ticket for each sample to be submitted. Complete all applicable blocks up to the "Remarks" block. Show the kind of test(s) performed and the result(s) in the "Nonmonitoring" blocks. Show in the "Remarks" block, "Aflatoxin Supervision," and, if a sublot, the sublot number.

3. Place one-half of the file sample and the original and one copy of the Grain Sample Ticket in a plastic bag and seal.

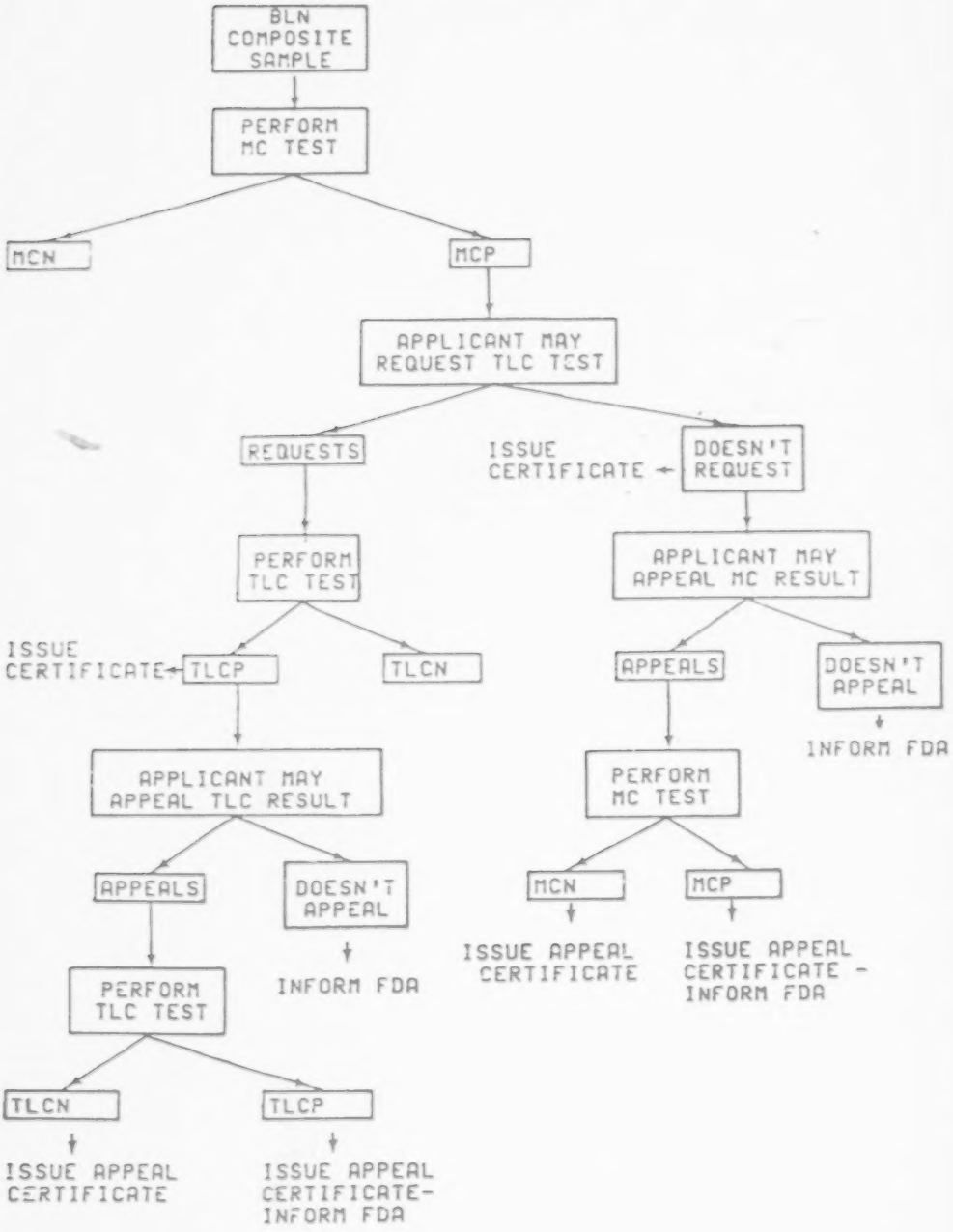
4. Mail the sample to CTS in a canvas bag. (See health and safety rules under exhibit E if samples tested MCP or TLCP.) Show "AFT Supervision" on the reverse side of the mailing tag.

B. CTS will test the sample for aflatoxin, record the result on the Grain Sample Ticket, and return a copy of the form.

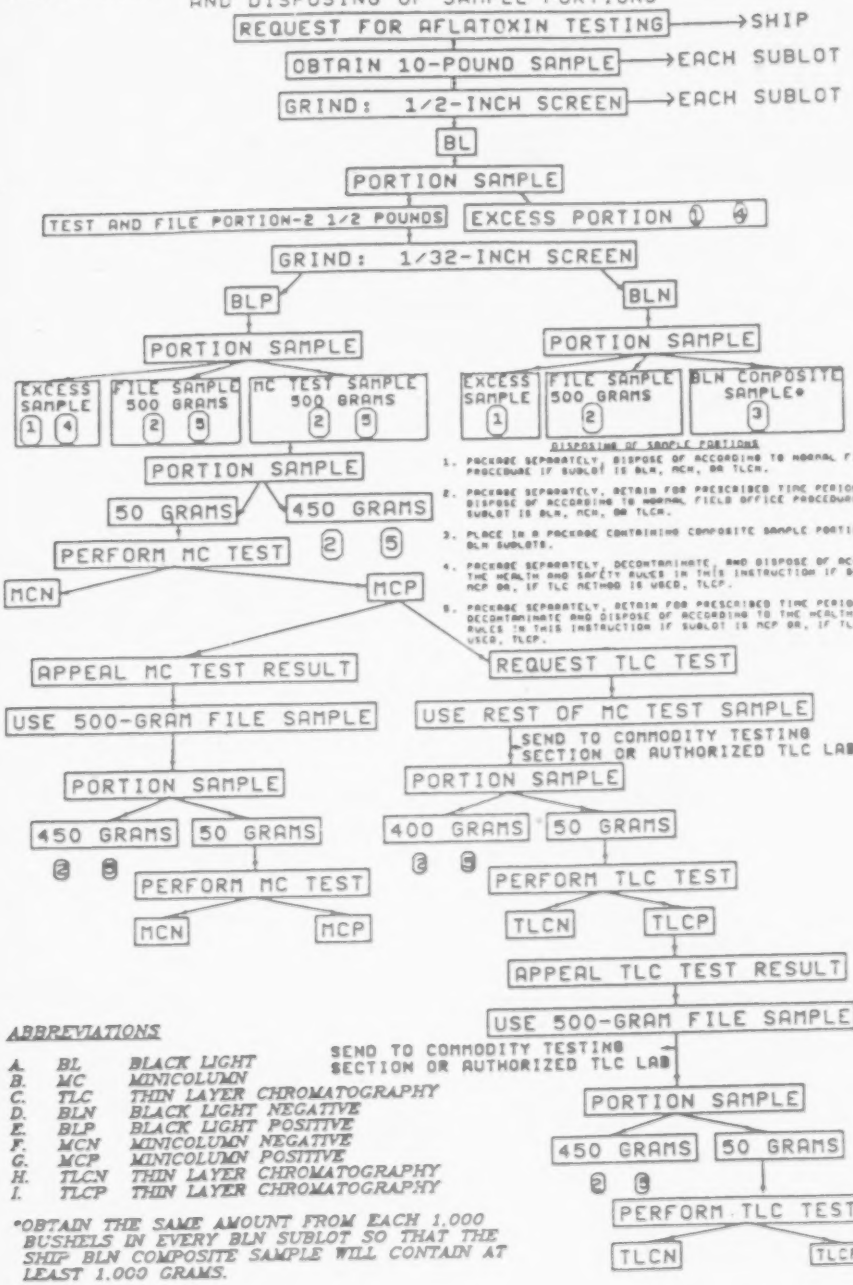
John W. Marshall

Director
Field Management Division

SHIP BLN COMPOSITE SAMPLE



PORTIONING OF SHIP SUBLOT AND SHIP BLN COMPOSITE SAMPLES AND DISPOSING OF SAMPLE PORTIONS


REQUEST FOR AFLATOXIN TESTING
SHIP
OBTAIN 10-POUND SAMPLE
EACH SUBLOT
GRIND: 1/2-INCH SCREEN
EACH SUBLOT
BL
PORTION SAMPLE
TEST AND FILE PORTION-2 1/2 POUNDS
EXCESS PORTION 1 4
GRIND: 1/32-INCH SCREEN
BLP
BLN
PORTION SAMPLE
PORTION SAMPLE
EXCESS SAMPLE 1 4
FILE SAMPLE 500 GRAMS 2 5
MC TEST SAMPLE 500 GRAMS 2 5
EXCESS SAMPLE 1
FILE SAMPLE 500 GRAMS 2
BLN COMPOSITE SAMPLE* 3
PORTION SAMPLE
50 GRAMS
450 GRAMS 2 5
PERFORM MC TEST
MCN
MCP
APPEAL MC TEST RESULT
USE 500-GRAM FILE SAMPLE
PORTION SAMPLE
450 GRAMS 2 5
50 GRAMS
PERFORM MC TEST
MCN
MCP
REQUEST TLC TEST
USE REST OF MC TEST SAMPLE
SEND TO COMMODITY TESTING SECTION OR AUTHORIZED TLC LAB
PORTION SAMPLE
400 GRAMS 2 5
50 GRAMS
PERFORM TLC TEST
TLCN
TLCP
APPEAL TLC TEST RESULT
USE 500-GRAM FILE SAMPLE
SEND TO COMMODITY TESTING SECTION OR AUTHORIZED TLC LAB
PORTION SAMPLE
450 GRAMS 2 5
50 GRAMS
PERFORM TLC TEST
TLCN
TLCP
DISPOSING OF SAMPLE PORTIONS
1. PACKAGE SEPARATELY, DISPOSE OF ACCORDING TO NORMAL FIELD OFFICE PROCEDURE IF SUBLOT IS BLN, MCN, OR TLCN.
2. PACKAGE SEPARATELY, RETAIN FOR PRESCRIBED TIME PERIOD, AND DISPOSE OF ACCORDING TO NORMAL FIELD OFFICE PROCEDURE IF SUBLOT IS BLN, MCN, OR TLCN.
3. PLACE IN A PACKAGE CONTAINING COMPOSITE SAMPLE PORTIONS FROM BLN SUBLOTS.
4. PACKAGE SEPARATELY, DECONTAMINATE, AND DISPOSE OF ACCORDING TO THE HEALTH AND SAFETY RULES IN THIS INSTRUCTION IF SUBLOT IS MCP OR, IF TLC METHOD IS USED, TLCP.
5. PACKAGE SEPARATELY, RETAIN FOR PRESCRIBED TIME PERIOD AND THEN DECONTAMINATE AND DISPOSE OF ACCORDING TO THE HEALTH AND SAFETY RULES IN THIS INSTRUCTION IF SUBLOT IS MCP OR, IF TLC METHOD IS USED, TLCP.

*ABBREVIATIONS*

| | | |
|---|---|---|
| A. | BL | BLACK LIGHT |
| B. | MC | MINICOLUMN |
| C. | TLC | THIN LAYER CHROMATOGRAPHY |
| D. | BLN | BLACK LIGHT NEGATIVE |
| E. | BLP | BLACK LIGHT POSITIVE |
| F. | MCN | MINICOLUMN NEGATIVE |
| G. | MCP | MINICOLUMN POSITIVE |
| H. | TLCN | THIN LAYER CHROMATOGRAPHY |
| I. | TLCP | THIN LAYER CHROMATOGRAPHY |

**OBTAIN THE SAME AMOUNT FROM EACH 1,000 BUSHELS IN EVERY BLN SUBLOT SO THAT THE SHIP BLN COMPOSITE SAMPLE WILL CONTAIN AT LEAST 1,000 GRAMS.*

4-25-85

Criteria for an Approved Aflatoxin Laboratory

The MC test for the determination of aflatoxin requires the use of flammable liquids and suspected carcinogens. FGIS will provide this service onsite only in facilities that provide protection to FGIS employees.

Individual elevators may provide two kinds of space for FGIS personnel to perform onsite MC aflatoxin testing. The space may be located (1) in a building along with other occupants or (2) in a building devoted exclusively to laboratory space. The requirements in each case are different.

In either case, the plan for the space to be used, approximately 100 square feet, is subject to inspection and approval by FGIS prior to beginning construction. FGIS will be available to review plans and suggest ways to comply with the requirements. Please note that the following are minimum requirements.

A. Where the proposed aflatoxin laboratory is located in a building with other occupants, the following minimum conditions shall be met:

1. Location - The laboratory shall be located at least 100 feet from the base of the elevator headhouse. This distance will be subject to negotiation when the elevator uses exterior grain legs and/or inclined belts in lieu of interior grain legs, or where the headhouse is equipped with blow-out panels.

2. Separation - The laboratory shall be isolated from nonlaboratory occupants by a fire barrier having at least a 1-hour fire resistance. The barrier will consist of floors, ceilings, and interior walls. All passageways and other openings that lead to adjacent interior space shall be provided with self-closing fire doors having a 1-hour fire resistance. These doors shall not be blocked open. Finally, the space must be separated from central heating, ventilation, and air-conditioning by automatic-closing fire dampers in the heating, ventilation, and air-conditioning ducts near the fire barrier, or by the use of a separate heating, ventilation, and air-conditioning system for the laboratory.

3. Electrical System - The laboratory space shall be provided with electrical power and lighting meeting the standards of the National Electrical Code. A three-wire system consisting of an energized wire, a neutral wire, and a grounding conductor will be satisfactory. Overhead lighting fixtures shall be installed through a ceiling that serves as a fire barrier. Fixtures suspended below such ceilings are acceptable. Wiring suitable for a Class I location is not required.

4. Plumbing - The laboratory space shall be provided with a basin having hot and cold potable water and a sewer connection.

5. Hood Duct Connections - The laboratory space shall be situated so that hoods, to be supplied by FGIS, can be ducted to the exterior of the building. The ducting will require a 6- or 8-inch diameter opening either vertically through the ceiling and roof or horizontally through an exterior wall.

B. Where the proposed aflatoxin laboratory is located in a small building used exclusively for this purpose, the following minimum conditions shall be met:

1. Location - The laboratory structure shall be at least 100 feet from the base of the elevator headhouse. This distance will be subject to negotiation when the elevator uses exterior grain legs, inclined belts, or where the headhouse consists of a lightly covered framework.

2. Separation - Where a separate structure is devoted exclusively to laboratory use, there is no need or requirement for a fire barrier. Likewise, fire resistant doors and windows and fire dampers in heating, ventilation, and air-conditioning ducts are not required.

3. Electrical System - The laboratory structure shall be provided with electrical power and lighting meeting the standards of the National Electrical Code. A three-wire system consisting of an energized wire, a neutral wire, and a grounding conductor will be satisfactory. Wiring suitable for a Class I location is not required.

4. Plumbing - The laboratory structure shall be provided with a basin having hot and cold potable wat[illegible] and a sewer connection.

5. Hood Duct Connections - The laboratory structure shall be arranged so that hoods, to be supplied by FGIS, can be ducted to the exterior of the structure. This will require a 6- or 8-inch diameter opening either vertically through the ceiling and roof or horizontally in an exterior wall.

Where the elevator provides laboratory space as prescribed, FGIS will provide the equipment and apparatus necessary for aflatoxin testing.

For further information about these requirements, contact the FGIS Safety and Health Staff.

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Exhibit D

## Holaday Velasco Method for the Determination of Aflatoxin in Corn

| MATERIALS 1/ | QUANTITY |
|---|---|
| Oster mixer; Model 848-31A; Oster Corp. | 2 |
| Process unit with sealing ring for Oster Mixer; Model 848-31A; Oster Corp. No. 937-45 | 2 |
| Bottom cap, threaded for Oster Mixer; Model 848-31A; Oster Corp. No. 937-46 | 2 |
| Viking Hammer Mill with a .../32" screen | 1 |
| Square type, 1-pt. Mason jars | 12 |
| Ultraviolet lamp viewing cabinet | 1 |
| Torsion balance | 1 |
| Dust mask suitable for nuisance dusts; 3M Model 3M Model 8710 or Moldex Model 2200 | 2 |
| Disposable polyethylene gloves, 100 per box; large; American Scientific Products No. G7236-30 | 2 boxes |
| Coats, laboratory, disposable; 25 per case; large size; American Scientific Products No. A6085-22 | 1 case |
| Two-gallon bucket (plastic) | 1 |
| Nalgene funnels - 80 mm Top I.D., Stem 30 mm Stem O.D. = 18 mm; American Scientific Products No. F7465-2 | 12 |
| Culture tubes - Disposable - 25 mm x 200 mm; 196 per case; American Scientific Products No. 14-915H | 1 case |
| Test tube rack; capable of holding 25 mm x 200 mm culture tubes; 11-1/2" x 4-3/4" x 3-5/8"; American Scientific Products No. S9224-4 | 3 |
| Riffle sampler (size: 50 x 24); Fisher Scientific No. 04-942D | 1 |
| Folded filter paper, 24 cm diameter; 100 per box; American Scientific Products No. F-2875-24 | 6 boxes |

1/ The mention of firm names or trade products does not imply that they are endorsed or recommended by the U.S. Department of Agriculture over other firms or similar products not mentioned. Except for the respirator, equivalent equipment may be used in place of items listed.

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Exhibit D

| MATERIALS | QUANTITY |
|---|---|
| Disposable weighing boats; large; 500 per package; American Scientific Products No. B2045-15 | 1 package |
| Cylinders, polypropylene, graduated | |
| 50 milliliter capacity | 1 |
| 100 milliliter capacity | 2 |
| 250 milliliter capacity | 1 |
| 1000 milliliter capacity | 1 |
| Bottle, nalgene, polypropylene, storage - 1000 ml capacity with caps; American Scientific Products No. B 7533-32 | 2 |
| Bottle, nalgene, polypropylene, 1/2 gallon capacity; Fisher Scientific No. B7538-64 | 1 |
| Carboy, nalgene, polyethylene, with spigot, 2-gallon capacity; Fisher Scientific No. 02-963-6A | 1 |
| Vortex mixer; American Scientific Products No. S822S | 1 |
| Vials, Kimble (size 21 mm x 50 mm), 36 per box; American Scientific No. B7811-3 | 1 box |
| Eppendorf pipette, 1000 microliter; American Scientific Products No. P5062-IL | 1 |
| Disposable pipette-tips for Eppendorf pipette; 1000 per box; American Scientific Products No. P5059-801 | 1 box |
| Jar, 1 polyethylene, 2-liter capacity; Fisher Scientific No. 11-815-11A (Apply a layer of Drierite to cover the bottom of the jar at time of opening of a 25-unit package of prepared minicolumns. Keep unused columns from an opened package in this covered jar. Change the Drierite every 2 weeks.) | 1 |
| Minicolumn stand; Mycolab No. 751; Mycolab Company, P.O. Box 321 Chesterfield, Missouri 63017 | 1 |
| Prepared minicolumns; 25 per package; Mycolab No. 201; Mycolab Company, P.O. Box 321 Chesterfield, Missouri 63017 | 4 packages |
| Glass wool, fiber; American Scientific Products No. G 6010 | 1 pound |
| Beakers, polypropylene, graduated, 250-ml capacity; American Scientific Products No. B2722-250 | 2 packages |

| II | CHEMICALS | QUANTITY |
|---|---|---|
| | Acetic acid, glacial, reagent grade | 500 milliliters |
| | Acetone, reagent grade | 500 milliliters |
| | Chloroform, reagent grade | 500 milliliters |
| | Drierite ($CaSO_4$) | 500 grams |
| | Florisil | 500 grams |
| | Household bleach | 2 gallons |
| | Methanol, purified or reagent grade | 1-gallon container or equivalent |
| | Silica gel | 500 grams |
| | Sodium chloride (reagent grade) | 1 kilogram |
| | Sodium sulfate, granular | 500 grams |
| | Toluene, reagent grade | 500 milliliters |
| | Zinc acetate, reagent grade | 500 grams |
| | Alumina, neutral, for column chromatography | 454 grams |

III PREPARATION OF SOLUTIONS

A. Methanol-Water: Using the 1000-ml graduated cylinder, add 2400 ml of methanol to the 2-gallon carboy with spigot. Then add 600 ml of tap water. Mix well. Label: "80 percent methanol in water."

B. Salt Solution: Using the 1/2-gallon polypropylene bottle, dissolve 225 g of sodium chloride and 225 g of zinc acetate in 1500 ml of tap water. Add 5.6 ml of glacial acetic acid to this solution, using the 50 ml graduated cylinder. Shake well. Label: "Salt Solution."

C. Chloroform - Acetone Solution: Pour 225 ml of chloroform and 25 ml of acetone into one 1000-ml polypropylene storage bottle. Shake well. Label: "Chloroform-Acetone Solution."

D. Standard Aflatoxin Solution: Supplied by FGIS Standardization Division (USDA, FGIS, Standardization Division, Richards-Gebaur AFB, Building 221, Grandview, Missouri 64030). STORE IN REFRIGERATOR WHEN NOT IN USE.

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Exhibit D

IV MINICOLUMN PROCEDURE

NOTE: ALL OF THE FOLLOWING SHALL BE PERFORMED INSIDE THE FUME HOOD. STRICT ADHERENCE TO THE FOLLOWING PROCEDURES IS ESSENTIAL.

A. Test Procedure.

1. Transfer the 50-g weighed sample into the 1-pint square-type Mason jar that comes with the Oster blender and add exactly 100 ml of the methanol-water solution, using a 100-ml graduated cylinder. Screw on the blender top using two sealing rings. Examine the rubber sealing rings to be sure there are no leaks around the Mason jar lid.

2. Invert the jar and blend 1 minute at high speed using the Oster blender. Remove from the blender.

3. Mark the culture tubes on the outside with a grease pencil to indicate the 15-ml and the 30-ml level. Do this by adding exactly 15 ml of water measured in a graduated cylinder to one tube and mark the level. Add an additional 15 ml of water to the same tube and mark the 30-ml level. Pour out the water and mark the rest of the culture tubes to be used in a day at the exact same height to indicate the 15-ml and 30-ml marks.

4. After mixing, filter the contents of the Mason jar through filter paper inserted in a funnel and collect the filtrate in a premarked culture tube to the 15-ml mark. Remove the funnel with the filter paper.

5. Add 15 ml of salt solution to the 15 ml of filtrate (up to the premarked 30-ml mark).

6. Shake the tube and contents vigorously for 10 seconds by hand or by using the Vortex-Genie mixer. To be properly mixed, the solution should form a clearly visible vortex the entire depth of the solution.

7. Filter the solution, after mixing, into a second culture tube using filter paper and funnel. Collect 15 ml of the filtrate (up to the first mark on the tube). Remove the funnel with filter paper.

8. Add 3 ml of toluene, using an Eppendorf pipette. This will require three transfers at 1 ml each.

9. Shake the solution in the tube gently for 10 seconds using a swirling motion. Make sure the toluene is mixed with the entire solution. Then let the layers separate.

10. Select a minicolumn and support it by using a support rack to hold the column in an upright position. Remove the cotton plug from the top of the prepared minicolumn with a long wire hooked at one end. Use a glass vial to catch the waste solvent from the column.

11. Pipette 1 ml of the top, toluene layer of the culture tube into a prepared minicolumn using the Eppendorf pipette with disposable tip. TAKE CARE TO DRAW ONLY FROM THE TOP LAYER OF THE CULTURE TUBE.

12. Let this extract drain into the column and then add 3 ml of chloroform-acetone solution and let drain into a vial. Simultaneously, prepare a minicolumn using 1 ml of the standard aflatoxin solution supplied by the Standardization Division. (Place a mark on the standard solution container at the point where maximum concaveness occurs immediately after drawing 1 ml of solution. Before using the solution again, check the solution level to make sure that it is even with the last mark. If it is not, do not use the solution and contact the Standardization Division immediately.) Treat this standard column the same way with 3 ml of chloroform-acetone solution and let drain.

13. Examine the sample minicolumn and the standard minicolumn for a blue fluorescent band at the top of the florisil layer. Be careful, some samples containing no aflatoxin show a faint white, yellow, or brown fluorescent band at the top of the florisil layer. If the band has no bluish tint, the sample is considered negative. If the band is equal in intensity to the standard minicolumn band, the sample is 20 ppb (negative). If the sample minicolumn band is more intense than the standard minicolumn, the sample is considered positive. Contact the Standardization Division immediately when there is a question regarding the intensity of the blue fluorescent band in the standard minicolumn. The Division will send a referee column immediately.

IN THE EVENT THAT MYCOLAB COLUMNS ARE IN SHORT SUPPLY, YOU MAY PREPARE YOUR OWN BY USING THE FOLLOWING METHOD: (NOTE: Empty Mycolab columns may be reused to prepare fresh minicolumns.)

B. Minicolumn Preparation (Holaday-Velasco).

1. Place a small plug of glass wool or glass beads used in prepacked columns in bottom of minicolumn to a depth of 5 mm.

2. With the aid of a funnel:

a. Using a small scoop, add sodium sulfate to a depth of approximately 5-7 mm.

b. Using the same small scoop, add florisil to a depth of 5-7 mm. Tamp tube to be sure additions are level.

c. Using a larger scoop, add two scoops of silica gel to a depth of approximately 20 mm.

d. Using the small scoop again, add neutral alumina to a depth of approximately 10 mm.

e. Using the small scoop, add 5-7 mm of sodium sulfate.

3. If you have prepared extra columns, place them in the polyethylene jar containing Drierite. Keep columns in an upright position. Store in a refrigerator when not actually in use.

HEALTH AND SAFETY RULES

A. Personnel working in the laboratory shall:

1. Store chemicals and equipment outside the hood.

2. Store only the standard aflatoxin solution, the minicolumn standards made from this solution, extra prepared minicolumns, and the black light standard in the refrigerator. Do not store food or drink in the refrigerator.

3. Store chemicals in places where they will not clutter bench tops or obstruct movements. Do not store solutions at a height exceeding 42 inches above floor level.

4. Label all bottles and containers.

5. Not smoke, eat, drink, and chew gum in the laboratory.

6. Wash hands immediately before eating, drinking, and smoking.

7. Wear a disposable wrap-around laboratory coat, disposable vinyl-type gloves, hard hat or disposable cap, and safety glasses when working. Laboratory coats should be reused until worn out or contaminated. (See item 18 below.)

8. Wear a disposable mask, 3M Model 8710 or Moldex Model 2200, at all times.

9. Not wear protective clothing outside of the laboratory.

10. Grind samples in an enclosure being exhausted with adequate velocity to confine and carry the particles away from the laboratory area.

11. Scan samples with BL only on a nonreflective flat surface.

12. Prepare solutions and perform analyses in a working fume hood.

13. Place used solvents (chloroform, acetone, toluene) and solutions in tightly-sealed, impermeable, labeled containers. Total quantity of waste chemicals in the laboratory shall not exceed 1 liquid gallon. Dispose of waste according to existing laws. If permitted by existing laws, solvents may be reduced in volume or disposed of by allowing them to evaporate from an open pan placed in an operating fume hood.

14. Place all used funnels and pieces of glassware in a bucket containing 5-6 percent hypochlorite solution (common, undiluted, household bleach). Wash in this solution for at least 15 minutes and thoroughly rinse with water before reusing.

15. Place all surplus samples and all sample portions from MCP sublots and lots in an impermeable container labeled "Biohazardous Material -Not to Be Used for Food or Foodstuff" and, if at the end of the file sample's expiration date the lot or sublot is MCP or TLCP, decontaminate. See exhibit C.

16. Decontaminate all contaminated waste with hypochlorite solution before disposal.

17. Clean areas and materials contaminated by the contents of broken aflatoxin solution, MC standard, and BL standard containers with a 5-6 percent hypochlorite solution. Use 1 part of bleach to 10 parts of spilled material. Contact time should be at least 15 minutes. Place decontaminated and cleaning materials in a sink, rinse with water, and flush liquid wastes to sanitary sewer. Place rinsed solid materials in a plastic waste bag, close tightly, and dispose of waste to a landfill disposal site.

Clean all chloroform spills immediately with an absorbent material and place absorbent material in the hood. When the chloroform has evaporated from the absorbent material, place absorbent material in an impermeable container and dispose of to a landfill waste disposal site.

18. Dispose of MC standard (column made from the aflatoxin standard solutions supplied by the Standardization Division) and, if a lot or sublot is MCP or TLCP, surplus sample, sweepings from around grinder, sample portions, filter paper, disposable pipette tips, disposable wrap around laboratory coat or apron (worn at the time of grinding and analyses), and gloves by placing in a plastic bag. Place the plastic bag inside a second bag and close tightly. Label the bag "Toxic Material" and dispose to a landfill disposal site.

If a washable laboratory coat is worn during the grinding and analyses, place the laboratory coat in a laundry bag for washing and have the coat washed before wearing it again.

19. While wearing disposable polyethylene gloves, wipe down the working areas and all surfaces of the room where aflatoxin dust is likely to have settled with 5-6 percent hypochlorite solution, at the end of each work day, to decontaminate them if a lot or sublot on that day was found to be MCP. Decontaminate at other times designated by the office manager.

20. Ship samples to CTS in a double container.

B. Personnel visiting a laboratory in which samples are being ground in preparation for aflatoxin analysis or analyzing samples for aflatoxin or both shall abide by the rules specified under "A" above.

C. The field office manager shall:

1. Provide a nonreflective, flat surface for BL scanning.

2. Provide impermeable metal containers meeting Underwriters Laboratory approval for Class I liquids that can be tightly sealed and which are labeled "Flammable" or "Biohazardous Material" or both, as applicable, for storing:

a. Waste toluene, acetone, chloroform, and solutions.

b. Decontaminated materials.

3. Contact an Environmental Protection Agency (EPA)-approved or an EPA-certified waste disposal company and make arrangements for removal of decontaminated material or provide other suitable waste disposal procedures consistent with existing laws that do not create a hazard to the community.

4. Provide laboratory signs as follows:

a. Laboratory door - "Biohazardous Material Present;" "No Smoking, Eating, and Drinking;" "Dust Masks, Laboratory Coats, Safety Glasses, and Vinyl-type Gloves Required;" "Flammable Material Present."

b. Refrigerator - "Biohazardous Material Present."

5. Limit the total amount of flammables (acetone, methanol, and toluene) in a laboratory at any one time, to not over 2 gallons.

6. Establish through the Training Officer, a training program for laboratory employees upon initial assignment of duties or upon institution of the training program to include:

a. Information conveying operations and conditions which can result in exposure to aflatoxin;

b. Necessary steps to protect against aflatoxin, including personal hygiene, personal protection equipment, and methods of decontamination;

c. Purpose, proper care, and limitations of dust masks and other protective equipment;

d. Purpose and description of the medical surveillance program;

e. Engineering and work practice controls, including cleaning methods; and

f. Review of USDA guidelines.

7. Maintain the following safety and health records:

a. Records of any employee injury or illness involving over exposure to chemicals (29 CFR 1904; 29 CFR 1960.66 thru .77b).

b. List of employees assigned to perform aflatoxin tests.

c. Copies of any safety and health studies pertaining to the laboratory.

MEDICAL EXAMINATIONS

I. All employees assigned to perform aflatoxin tests involving the use of chemicals will require baseline and annual medical examinations. The baseline should be completed prior to assignment to duties involving use of aflatoxin test chemicals. The annual test shall be conducted during the month in which the employee was born.

II. Tests required:

A. Audiogram.

B. Blood chemistry screen (liver function tests).

C. CBC.

D. Urinalysis.

E. Sputum cytology.

F. Urine sediment cytology.

G. Medical history with special attention to the use of alcohol.

H. Chest x-ray if recommended by examining physician.

III. Medical Records and Reports

A. Medical reports and records will not be sent to the field office, and no one at the field office except the employee is authorized access to information obtained during the physical examination.

B. Medical reports and records prepared by the examining physician are to be sent directly to:

Medical Officer
U.S. Department of Agriculture
1400 Independence Avenue, S.W., Room 1039-S
Washington, D.C. 20250

The envelope must be marked CONFIDENTIAL MEDICAL RECORDS TO BE OPEN BY ADDRESSEE ONLY.

C. The medical office will review the records and inform the Safety and Health Manager of any individual whose medical condition precludes assignment to work around aflatoxin test chemicals. The Safety and Health Manager will advise the field office manager of the restrictions.

D. Costs associated with the physical examination shall be paid by the field office.

United States Department of Agriculture
Federal Grain Inspection Service

**Program Bulletin** 89.1 1-12-89

AFLATOXIN TESTING SERVICES

I. PURPOSE

This program bulletin announces the availability of:

* More timely aflatoxin testing service at interior locations;

* Special submitted sample inspection service that will allow for the identity of a carrier to be shown on a submitted sample inspection certificate under certain conditions; and

* Modified minicolumn procedures that will indicate if a lot is contaminated at a certain level or range.

II. GENERAL INFORMATION

The 1988 drought increased the possibility for aflatoxin contamination in this year's corn crop. In response to this potential problem, FGIS enhanced its aflatoxin testing services to provide more timely and useful service throughout the corn producing areas of the United States.

This bulletin modifies certain procedures in the current FGIS Instruction 918-39, "Testing Corn for Aflatoxin", such as, billing and certification, and shall be used in conjunction with the current instruction.

III. HOW TO REQUEST SERVICE

A. General. Some FGIS field offices are not equipped to provide MC or TLC testing service. However, these field offices will forward samples to designated FGIS aflatoxin laboratories. Interested persons may request:

1. Official sample lot inspection service; whereby, local FGIS personnel will sample the grain and forward the sample to a designated aflatoxin laboratory;

2. Submitted sample inspection service; whereby, the applicant sends a sample to the local FGIS field office or directly to a designated aflatoxin laboratory; or

3. Special submitted sample inspection service; whereby, the applicant requests a designated or delegated agency to sample the grain and send the sample to the local FGIS field office or directly to a designated aflatoxin laboratory. This service allows interested

persons to obtain a submitted sample inspection certificate that shows the identity of the carrier in the form of a special statement when the sample is obtained and handled by official personnel.

B. Requests. Applicants for aflatoxin testing service shall specify:

1. The type of service desired under A above;

2. The method of analysis desired, i.e., MC, modified MC, or TLC; and

3. Whether to send test samples overnight to the testing laboratory. The cost of overnight service will be added to the total service cost.

C. Aflatoxin laboratories. FGIS aflatoxin laboratories in Mobile, Alabama, and Norfolk, Virginia, serve as the primary testing laboratories for interior aflatoxin testing service. They also provide, along with the Lutcher, Louisiana; Belle Chasse, Louisiana; and Beltsville, Maryland, laboratories, TLC testing for export locations. As indicated below, the Mobile and Norfolk laboratories are dedicated to servicing specific field office circuits in the U.S. corn producing areas.

| | Offices serviced |
|---|---|
| Mobile | Cedar Rapids |
| | Kansas City |
| | Minneapolis |
| | Omaha |
| Norfolk | Indianapolis |
| | Peoria |
| | St. Louis |

Applicants wishing to send a sample to an aflatoxin testing laboratory directly should contact their local field office for further information. Field offices not listed above or with questions should contact their respective area program chief.

IV. WORKSHEETS Use form FGIS 992, "Services Performed Report", when sending samples to another FGIS office for analysis. Include the following information:

1. Field Office
2. Type Sample
3. Applicant
4. Identification
5. When applicable, "special submitted sample statement required."
6. Other pertinent information in remarks.

V. FIELD OFFICE RESPONSIBILITY

A. Without mills. Field offices without a Hammer Mill 1/ or Romer Mill 1/ that receive requests for aflatoxin testing shall forward a minimum 10-pound (approximately 4,540 grams) sample to a designated aflatoxin testing laboratory. Obtain official sample-lot samples according to Book I, Grain Inspection Handbook guidelines.

B. With mills. Field offices with a Viking Hammer Mill 1/ or Romer Mill 1/ shall grind the official sample-lot or submitted samples according to the procedures outlined in FGIS Instruction 918-39. From the ground portion, obtain a representative sample of not less than 300 grams. Send the sample, the completed worksheet (FGIS-992), and a copy of the application or specific instructions on the type of service and testing methodology requested to the specified aflatoxin testing laboratory.

Note to Romer Mill users: (1) The Romer mill will automatically divide the ground corn into three seperate portions. Due to partical segregation, thoroughly mix the portion from which the final ground sample will be drawn using a riffle divider or a sanitary ladle or spoon. (2) To prevent damage to the mill, do not grind samples that contain 20 percent or more moisture; send the entire unground sample to the testing laboratory in this case.

C. Testing Offices. Designated aflatoxin testing offices shall:

1. Analyze samples according to the test procedures established in FGIS Instruction 918-39 or, upon request, analyze the sample according to the modified MC test method established by this bulletin.

2. Record the results on the FGIS-992 and inform the originating office and/or the applicant of the results via telephone.

3. Certify results and bill applicant according to the procedures established in FGIS Instruction 918-39. The testing office shall issue certificates and bill the applicant for services performed unless otherwise arranged by the involved field offices. For the special submitted sample service, certificate the results and

1/ The mention of firm names or trade products does not imply that they are endorsed or recommended by the U.S. Department of Agriculture over other firms or similar products.

show in the "Remarks" section of the certificate the following statement:

"The sample identified above was officially sampled under the United States Grain Standards Act, as amended, from a carrier identified as (carrier identification)."

VI. DESIGNATED AND DELEGATED AGENCY RESPONSIBILITIES

Designated or delegated agencies requested to officially sample corn under the United States Grain Standards Act for submission to FGIS for aflatoxin testing shall:

A. Obtain a sample (minimum 10 pounds or 4,540 grams) following the sampling procedures in Book I of the Grain Inspection Handbook.

B. Enclose documentation with each sample, indicating that the applicant requests that the sample be considered a special submitted sample and that the carrier identification statement be shown in the "Remarks" section of the certificate. Also, provide the carrier identification and the applicant's name, address, and phone number.

C. Mail the sample to FGIS or give the sample to the applicant.

D. When the sample is given to the applicant for delivery to FGIS, place the sample and documentation inside a sealable, shipping container; seal the container; and maintain a record of the seal number.

VII. MODIFIED MC METHOD

A. General. This service is available on a request basis only; otherwise, the standard FGIS operating procedures (FGIS Instruction 918-39) for performing MC at the 20 ppb level will apply.

Applicants may request an aflatoxin analysis, utilizing the modified MC procedure, that indicates if the lot contains aflatoxin at levels greater than 10, 100, 200, or 300 ppb.

B. Procedure for detecting aflatoxin contamination greater than 10 ppb.

1. Using the Eppendorf pipette, transfer 1 ml of aflatoxin B1 standard solution provided by the Quality Assurance and Research Division (QARD) to a clean, dry, 8 ml vial.

2. Place a clean tip on the Eppendorf pipette, add 1 ml of fresh toluene to the same vial.

3. Place a teflon-coated cap onto the vial and shake it vigorously until the solution is well mixed (approximately 15 seconds).

4. Using the Eppendorf pipette, transfer 1 ml of this diluted standard solution into a clean MC. Allow it to drain into the column, then add 3 ml of chloroform/acetone solution. Save this column as the reference standard (10 ppb "standard column").

5. Perform a MC test of the corn sample using the current MC procedure.

6. Using a UV lamp, compare the fluorescence of the MC from the sample tested with that of the "10 ppb standard" column (prepared in step 4 above). If the fluorescence of the sample column is equal to or less than that of the "10 ppb standard" column, use the following statement:

> "Aflatoxin equal to or less than 10 ppb basis minicolumn method. This analysis reflects the aflatoxin level at the time the test was performed and may not reflect the level at a future date."

If the fluorescence of the sample column is greater than the "10 ppb standard" column, use the following statement:

> "Aflatoxin exceeds 10 ppb basis the minicolumn method. This analysis reflects the aflatoxin level at the time the test was performed and may not reflect the level at a future date."

C. Procedures for detecting aflatoxin contamination greater than 100, >200, and >300 ppb. Follow the existing procedures in FGIS Instruction 918-39, when testing to the normal 20 ppb level. These procedures apply when testing to 100, 200, and 300 ppb.

1. Label three clean, dry, 8 ml vials #1, #2, and #3. Place them in the vial rack.

2. Using the 1,000 microliter (1 ml) Eppendorf pipette, transfer 1 ml of the toluene extract from the top layer remaining in the test tube from the original analysis into vial #1.

a. Using a clean tip on the Eppendorf pipette, add 4 ml of fresh toluene to this vial. (This can be accomplished by placing several milliliters of toluene in a small clean glass beaker then making 4 transfers with the 1 ml Eppendorf pipette.) Cap the vial with a teflon lined cap, shake vigorously until the solution is well mixed (approximately 15 seconds).

b. Using a clean tip on the Eppendorf pipette, transfer 1 ml of the solution from vial #1 to a clean MC. Allow the solution to drain into the column then add 3 ml of chloroform/acetone solution.

c. Using a UV lamp, compare the fluorescence of this column with the "20 ppb standard" column. If the fluorescence of the sample column is equal to or less than the "20 ppb standard" column, use the following statement:

> "Aflatoxin exceeds 20 ppb but does not exceed 100 ppb basis minicolumn method. This analysis reflects the aflatoxin level at the time the test was performed and may not reflect the level at a future date."

If the fluorescence of the sample column is greater than the "20 ppb standard" column, proceed to Step 3.

3. Using a clean tip on the Eppendorf pipette, transfer 1 ml of the solution from vial #1 to the vial labeled #2. Replace the cap on vial #1 to avoid evaporation of the sample, set aside.

a. With a clean tip on the Eppendorf pipette, add 1 ml of fresh toluene to vial #2. Cap the vial with a teflon lined cap and shake vigorously until the solution is well mixed (approximately 15 seconds).

b. Using a clean tip on the Eppendorf pipette, add 1 ml from vial #2 to a new MC. Allow the toluene solution to drain into the column then add 3 ml of chloroform/acetone solution.

c. Using a UV lamp, compare the fluorescence of this column with that of the "20 ppb standard" column. If the fluorescence of the sample column is equal to or less than the "20 ppb standard" column, use the following statement:

"Aflatoxin exceeds 100 ppb but does not exceed 200 ppb basis minicolumn method. This analysis reflects the aflatoxin level at the time the test was performed and may not reflect the level at a future date."

If the fluorescence of the sample column is greater than the "20 ppb standard" column, proceed to Step 4.

4. Using a clean tip on the Eppendorf pipette, transfer 1 ml of the solution from vial #1 to vial #3.

a. Using a clean tip on the Eppendorf pipette, add 2 ml of fresh toluene to vial #3, cap the vial with a teflon lined cap, and shake vigorously until the solution is well mixed (approximately 15 seconds).

b. With a clean tip on the Eppendorf pipette, add 1 ml of the solution from vial #3 to a new MC. Allow the solution to drain into the column then add 3 ml of chloroform/acetone solution.

c. Using a UV lamp, compare the fluorescence of this column with the "20 ppb standard" column. If the fluorescence of the sample column is equal to or less than the "20 ppb standard" column, use the following statement:

"Aflatoxin exceeds 200 ppb but does not exceed 300 ppb basis minicolumn method. This analysis reflects the aflatoxin level at the time the test was performed and may not reflect the level at a future date."

If the fluorescence of the sample column is greater than the "20 ppb standard" column, use the following statement:

"Aflatoxin exceeds 300 ppb basis minicolumn method. This analysis reflects the aflatoxin level at the time the test was performed and may not reflect the level at a future date."

When the modified MC method is requested, there is no additional charge. The standard charge of $18.90 applies for the entire test.

VIII. NOTIFYING FDA

FGIS field offices that perform aflatoxin tests shall report all positive aflatoxin results (more than 20 ppb) on official lot inspections and special submitted sample inspections (those that provide for including the carrier identification statement) to the Food and Drug Administration in accordance with FGIS Instruction 918-39, Testing Corn for Aflatoxin, dated April 25, 1985, and Program Directive 906.2, Implementation of the FGIS-FDA Memorandum of Understanding, dated April 9, 1986.

If subsequent testing is scheduled (TLC of previous MC results, or retest/appeal), do not notify FDA until the final results are known.

IX. SAFETY INFORMATION

Existing health and safety guidelines outlined in the current instruction (FGIS Instruction 918-39) apply for additional testing procedures established in this bulletin. The current instruction requires safety glasses be worn by laboratory personnel when working. These glasses should be UV absorbing glasses when working with the UV lamp. The UV viewing cabinets equipped with a viewer port for examination of the MC or TLC plates do not require the use of the UV absorbing glasses.

X. REPORTING TLC RESULTS

When the TLC method is used for determining aflatoxin in corn, the following statement shall be shown on the certificate:

> "Aflatoxin (result) basis thin-layer chromatography method. This analysis reflects the aflatoxin level at the time the test was performed and may not reflect the level at a future date."

Use the following guidelines for recording results in the above statement.

If the results are 10 ppb or more, state the exact result in terms of parts per billions, e.g., "12 ppb."

If the results indicate presence of aflatoxin but the results do not exceed 10 ppb, state "does not exceed 10 ppb."

If the results indicate no aflatoxin, state the results as "not detected."

for Thomas E. Quinn
Director
Field Management Division

March 13, 1989

Memo to Greg Frazier

From Rod Leonard

Re: Aflatoxin

Dirty grain poses a health threat to American consumers, and harms American grain exports in a highly competitive world market.

Dirty grain is likely to be contaminated with aflatoxin, a substance secreted by mold that grows on grain. Aflatoxin is acknowledged by the Federal government as the most potent carcinogen yet discovered. The U.S. corn crop harvested in 1988 is extensively contaminated with aflatoxin, but the mold that produces the compound occurs routinely in crops that grow close to the ground. The U.S. experiences aflatoxin outbreaks — i.e., higher than normal levels — two to three times every decade, for a number of reasons. The 1988 corn crop has more aflatoxin because the corn was heavily damaged by the drought, and corn that is stressed is more vulnerable to mold growth.

The Food and Drug Administration (FDA) says that aflatoxin levels in food should not exceed 0.5 part per billion, and allows aflatoxin levels up to 300 parts per billion in animal feed, the level depending on the food use of the animal or animal product. Minute levels of aflatoxin — 0.05 parts per billion — cause tumors in test animals, and the compound has caused tumors in every animal tested, from rats to monkeys. Aflatoxin occurs in every country — i.e., mold spores are ubiquitous in the soil. It is more prevalent in the food crops grown in Africa and the Middle East where cancers of the digestive tract and the liver are commonly found, and which public health officials ascribe to aflatoxin. In the Southeast U.S., where aflatoxin is routinely found on peanuts and on other foods in local diets, higher than normal levels of mental retardation are linked with aflatoxin.

Federal and state governments have generally looked the other way when an alfatoxin outbreak occurs, contending that little can be done. Some toxicologists, particularly European, argue that the rate of cancer deaths is as high as 500 per million (over the lifetime of the individuals exposed) with aflatoxin levels of 0.5 parts per billion.

The European Community, and the Russian and the Japanese now have placed aflatoxin standards on U.S. grain exports that range from a zero tolerance to no more than 20 parts per billion. Five parts per billion is a common minimum now applied to U.S. grain exports. Because of the concern of grain importers, U.S. grain

exports are highly sensitive to the aflatoxin threat. As a result, trade groups such as the U.S. Grain Council have developed special programs to help overseas buyers obtain grain with no or low levels of aflatoxin.

FDA, which has regulatory responsibility for grain shipped in interstate commerce, says it has found concentrations of aflatoxin above 20 parts per billion in only 6 percent of the corn it has tested. However, last September, when the current outbreak first surfaced, state agencies in Iowa, Illinois, Minnesota and elsewhere found that a third or more of the samples they tested had aflatoxin levels in excess of the 20 parts per billion. As the attached article from the Wall Street Journal reports, U.S. food companies that buy only clean grain — i.e., no aflatoxin — are having difficulty finding the grain they want, and are turning back an extensive volume of grain because it is contaminated.

The U.S. is having problems with grain quality — i.e., American consumers are concerned because of the threat to their health, and grain importers are insisting on quality standards higher than those acceptable to the Federal government. The reason is not that the 1988 crop is damaged; rather, it is that the United States has made no effort to deal with these conditions and is unprepared when they happen, as they do regularly.

U.S. grain sold in export markets has always been subject to complaints about poor quality. The complaints range from criticism of U.S. standards to charges that U.S. grain shippers add dirt, stones and other refuse to increase the tonnage and the profits. The new study by the Office of Technology Assessment on "kEnhancing the Quality of U.S. Grain for International Trade" is the most recent in-depth look at the problem. While the Department of Agriculture (USDA) has acknowledged the problems, the complaints could be dismissed in the post-World War II period because world markets have had little option other than to buy U.S. grain in the absense of other supplies. The situation changed markedly in the 1980s as other countries — particularly in the European Community, Latin America and Southeast Asia— began producing grain surpluses regularly which are sold as exports in competition with the U.S. Grain quality, which once was a question of dirt, broken kernels and other debris, now is being raised for its health implications, a much more serious competitive threat.

Grain quality has been largely ignored domestically, as well, however. Although FDA publicly insisted the maximum allowable level of aflatoxin in grain was 20 parts per billion, the standard was not enforced. In fact, until 1986 FDA had suppressed public information about the problems of aflatoxin, chosing instead to relax its alleged standards without public notice. During periods of high aflatoxin levels, state departments of agriculture would routinely request FDA approval to ship grain contaminated with levels exceeding 20 parts per billion, and FDA regularly concurred. The decisions were transmitted by letter, and the public was not informed.

In 1983, CNI and the Public Interest Law Center filed suit, charging FDA's action violated the Federal Food Drug and Cosmetic (FD&C) Act. The lawsuit asked the Federal courts to order FDA to

establish and enforce tolerances for aflatoxin — i.e., legally enforceable exposure levels — and to allow public comment on regulatory standards before they are adopted.

The U.S. Circuit Court of Appeals held that FDA was required to establish tolerances, an opinion overturned by the Supreme Court on appeal from FDA. The Circuit Court also directed FDA to disclose to the public when it establishes standards for aflatoxin, and to allow public comment. FDA did not appeal this ruling, but the agency said it would no longer issue standards. Instead, as it has done in the current aflatoxin outbreak, FDA said it would issue guidelines. In this instance, guidelines are to inform grain shippers, food processors and others handling grain of the levels of aflatoxin that would cause FDA to take legal action to prohibit in interstate commerce, if FDA were to take legal action. A copy of the guideline memo is attached.

In effect, FDA may or may not seek to protect the public from exposure to aflatoxin; if it chooses to, the guidelines will be the standards that FDA will ask to courts enforce.

In actual fact, FDA is a paper tiger; it has no enforcement policy or process through which it can regulate aflatoxin. An action under the guidelines would apply only to the individual firm and is enforceable against the individual firm only after FDA has presented evidence in a court case to prove that the aflatoxin exposure above in the level cited in the guideline is harmful. The injury to consumers which any court action would seek to avoid would already have occurred by the time FDA could get to court, and any single court action could potentially drag on for years, consuming agency resources which might be available for other enforcement actions. FDA may pretend it has the power to intimidate, but intimidation is not regulation.

Further, FDA has no confidence in its data regarding the risk to health posed by aflatoxin. The agency has promised to disclose its scientific data to the public, but it has steadfastly refused to defend the data in a public hearing. The reason is not entirely clear, but it suggests the exposure levels that FDA is willing to accept may pose a greater risk to health than FDA now acknowledges.

In addition, as the Wall Street Journal report concludes, "The chances of being caught violating FDA rules are slim, and the corn can make it to market no matter what....By the time test results (come) back weeks later, showing five times the aflatoxin considered safe for human consumption, the grain had long since been shipped down the Mississippi river..."

The ultimate irony of FDA's aflatoxin policy is that it spreads contamination from dirty grain to clean grain, rather than seeking to contain the threat. FDA encourages grain shippers who find they own grain that exceeds the agency's guidelines for aflatoxin to mix clean, uncontaminated grain with the dirty grain, thereby insuring greater more than minimizing exposure.

Perhaps this policy in earlier times might have seemed

justifiable to federal and state regulators who were concerned about the economic implications to farmers and regional economies dependent on agriculture. It prevades federal attitudes still: "The people who buy the corn — it's up to them to protect themselves," according to USDA officials.

In a world where the grain export market is fiercely competitive, as it is today and will only grow more so in the future, the old ways only invite economic disaster. Every competitor will eagerly point out the risk to buyers from American grain, even if their grain is no better, but American exports will suffer nonetheless. The danger, if not obvious to federal bureaucrats, is clearly understood by grain growers and exporters.

The danger to federal and state governments from inaction is compounded. American consumers are increasingly aware of the risks to health posed by aflatoxin, and will be increasingly vocal about their concern. They will feel cheated and deceived when they learn that other countries are enforcing higher standards on grain quality than the U.S. is willing to impose, and they will not hesitate to say so. Every time American consumers complain about the quality of American grain, the reports will reach foreign buyers and officials of other governments who, in turn, will be less inclined to buy the grain the American people do not trust.

The U.S. clearly needs a new policy on grain quality and safety, one intended to enhance the health and safety of consumers in the U.S. and around the world. If the U.S. exports its concern for health and safety, then it also will lead in grain exports.

This will involve several steps, including:

1. A federal-state protocol on grain quality standards that:
   a. Recognizes the priority of consumer health and safety;
   b. Requires the development of tolerances;
   c. Provides a collecting process to isolate the most heavily infested lots of grain;
   d. Prohibits mixing of contaminated with clean grain.
2. A network of federal-state testing stations adequate to provide test results within hours, rather than days or weeks;
3. Research to develop testing procedures to give test results before grain shipments are moved;
4. Research to develop methods, treatments and procedures to eliminate or reduce aflatoxin that render the grain safe to use;
5. Federal price support programs that provide bonuses for clean grain, with allowances for treating contaminated grain;
6. Research to establish the nature and relative risks of aflatoxin for humans.

DVEG

Dr Elizabeth Rose te Groen,
Route 2 Box 112,
Newburg MO 65550.
March 20 1989.

Congressman Glickman.
1212 Longworth HOB.,
Washington 20515.

MAR 29 1989

Dear Sir,

I was pleased to read in the Newsweek of March 6th that you considered the problem of aflatoxin in the corn to be serious enough to call for a house agricultural subcommitee on the subject.

I spent over 25 years in Africa studying the epidemiology of esophageal cancer. During that time I followed closely the studies on liver cancer and its relationship to the presence of Aflatoxin.

Both the Wall Street Journal and Newsweek underestimate the toxicity of this poison.

They state:

1) "It hasn't been proved to cause the disease (cancer) among humans". However the correlation between the quantities of Aflatoxin in the food and liver cancer in the people that eat that food is extremely high. people have been hanged on less evidence.

2) "Ten to twenty years from now there will be more human cancers because of this". It may not be so long, depending on the exposure and the dose. In areas where the Fungus is endemic primary cancer of the liver is a disease of the young affecting children as young as 3 years old.

3) " It (Aflatoxin) can be significantly reduced by cooking". Not so. It is heat stable, meaning it is not destroyed by heat. Therefore it is not destroyed in processed foods.

4)"Aflatoxin levels in meat are barely measurable" You bet. 0.5 parts per billion are barely measureable yet this is the highest standard allowed in milk by the FDA. One of the ugly characteristics of this toxin is that it does pass from the feed into the milk of the cows that fed on it. Thus the possibility of finding it in all diary products including cheese.

A synergic factor which affects the cancer rate in areas high in Aflatoxin is the presence of the Hepatitis B virus. This is as high as 10-15% of the population in Mozambique but it is also found in 5% of the people in the USA, which adds up to a large number of people that are susceptable to the influence of the aflatoxin.

I am enclosing an article I wrote for our local paper. I hope it may be of use to you.

There are two informative articles on the subject of Aflatoxin in food in relation to hepatocellular carcinoma worth your perusal:

1. "Hepatocellular Carcinoma and Dietary Aflatoxin in Mozambique and Transkei" by S.J Van Ransburg et al. Br. J. Cancer (1985), 51, 713-726.
2. "Role of Mycotoxins in Endemic Liver and Oesophageal Cancer" by S.J. van Rensburg. Paper presented at the sixth international symposium on Mycotoxins and Phycotoxins in Pretoria, RSA July 1985. 1986 Elsevier Science Publishers BV., Amsterdam, Netherlands.

Should you require any further details please let me know.

My address until the 12th of April will be:

c/o Peter TeGroen
1045 Georgetown road
Norfolk, Vergina. 23502.
Tel. (804) 461-5393.

Hoping this imformation will be of value to you in your deliberations.

Sincerely yours.

Elizabeth te Groen

Ofy to Bill Emerson

ROLLA DAILY NEWS
Sunday, March 19, 1989
Page 6, Section A

# Consumer Will Pay for Aflatoxin in Corn

guest commentary

Dr. Elizabeth Rose te Groen

It took two grapes to stop people eating fruit from Chile, but what will it take to stop last season's carcinogenic corn crop from reaching the unsuspecting consumer?

Conditions of drought and heat in the Midwest last year favored the infestation of corn with Aspergillus flavus, a fungus which under these ideal conditions produces aflatoxin, one of the most potent cancer-causing agents known to science, a hundred times more likely to cause cancer than any industrial pollutant.

Ducklings fed on a daily dose of a few millionths of a gram of Aflatoxin die in 10 days, rats in 68 weeks, primates in just over a year, and in Africa where the infestation is high in peanuts and other foods, children of 3 years old die of primary liver cancer.

Epidemiological studies in Mozambique showed a clear cut correlation between the incidence of liver cancer in the population and the infestation of aflatoxin in the foods.

The bad news is that this toxin is heat stable (not destroyed by cooking). This means that not only contaminated corn but all products [illegible] from that corn are affected. [illegible]tion the aflatoxin passes [illegible] and tissues of the [illegible] it, so that even cheese and other milk products become suspect.

Aflatoxin was first discovered in the early 1960s when turkeys in England died after eating infected grain imported from South America and from Africa. Since that time, human deaths from eating moldy grain have been reported from many parts of the world as far apart as India, Thailand and Kenya.

Our Midwest supplies one-third of the world's corn. One-third of the official samples taken from Iowa and Illinois have been found to contain dangerous levels of aflatoxin and, according to the Wall Street Journal, five other states in the corn belt also reported contamination, and the contamination spreads rapidly in the warm confines of storage elevators. One-quarter of the crop of September last year had been harvested before aflatoxin was detected. Grain in several elevators in the port of Baltimore was condemned and millions of gallons of tainted milk were dumped in Texas, Wisconsin and Illinois.

But the story does not end there. Infected grain is still around and much of it will find its way into breakfast cereals, cornmeal, tortilla chips, and other processed foods (the average American consumes about 160 pounds of corn and corn products each year). The corn is also finding its way into overseas markets.

Until last fall, the FDA considered more than 20 parts per billion in corn to be sufficient for legal action. Since October, it has allowed 300 parts per billion in [illegible] took had [illegible] levels in last year's crop [illegible] 1,300 per billion. Lately, the FDA's allowable limits have been fluctuating as they balance between selling poisonous foods on the one hand and delivering lifesaving food to the needy on the other.

There are three major concerns:

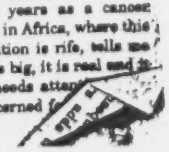
First, the consumer who pays good money for a bad product. No one would knowingly buy moldy corn, but the buyer has no way of detecting contamination in processed food.

Second, we are exporting moldy corn. Apart from tarnishing our image as a responsible exporter, there is the immorality of the action. For two grapes we have closed Chili's fruit export markets; how do we justify exporting tons of infected corn?

Third, is the farmer and his dilemma. Morality dictates this his crop be destroyed, but should he bear all the costs? Can we expect him to watch his animals starve, or will he feed them with infested corn, knowing full well that he will poison thousands of people with contaminated products; is it fair to expect him to choose between his family and the rest of the world? In spite of the deficit, this is one time the farmer should be offered compensation for the destruction of his toxic crop. Everyone would benefit.

For now it may be the farmer's loss, but ultimately, it is the consumer that will have to pay — either by the loss of his health or by increased prices when manufacturers insist that all stored corn be tested for aflatoxin before they buy.

Twenty-five years as a cancer epidemiologist in Africa, where this fungus infestation is rife, tells me this problem is big, it is real and it is urgent; it needs attention [illegible] are at all concerned for the health of our nation.



NEOGEN CORPORATION

MAR 14 1989

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March 7, 1989

The Honorable Dan Glickman
United States House of Representatives
1212 Longworth HOB
Washington, D.C. 20515

Dear Congressman Glickman:

I congratulate your recent decision to professionally study the aflatoxin problem. I agree with your statement that we should not get consumers panicked, but can't ignore what might be a serious problem.

Our company finds ourselves on the side of the agricultural producer and processor. However, we must all be concerned about food safety and I believe there is an increased awareness developing on an almost daily basis by food producers and processors on this subject. In the case of aflatoxin, I believe there is a great deal of confusion and misconception concerning the toxin itself and how it is being controlled. As an example, we have had grain suppliers advise us that they were issuing certificates to companies that their grain was aflatoxin free, though they had not tested it. They justify this by stating that FDA had been to their location in the past and not found "any problems." Therefore, they assumed the particular lot of grain they were shipping must be okay.

You may find my attached letter to the Newsweek writers to be interesting.

Cordially,

James L. Herbert
President

JLH:dak

Enclosure

620 Lesher Place • Lansing Michigan 48912 • 517/372-9200

NEOGEN CORPORATION

March 8, 1989

Mr. Ron Givens
Newsweek
200 E. Randolph
Chicago, Illinois 60601

Dear Mr. Givens:

I read with interest your article in the March 6 issue concerning aflatoxin concerns in the nation's food supply. Since our company is the largest supplier of new test kits for the detection of this toxin, I thought you might be interested in a few observations.

Biotechnology Impacts Testing

Aflatoxin has been recognized as a natural carcinogen for a number of years. However, until recently, little could be done to preclude it from the marketplace since testing required a number of hours, specialized equipment, and highly trained technicians. Therefore, samples were sent to distant labs and answers were not available for days. During this time, the grain had generally entered the system or had been co-mingled with thousands of bushels of other grain.

Because of the discovery of monoclonal antibodies and their use in colorimetric testing systems, it is now possible to run an aflatoxin test in 10 minutes at the farm or a grain elevator with non-technical personnel at a cost of under $10 per test. These tests are highly accurate and are capable of detecting the toxin at levels of 10 parts per billion or less.

Is Testing Adequate?

Your article states "The federal government has clear standards regarding how much aflatoxin can be in corn shipped between states." This is in fact a regulation, but just because the regulation is on the books, there is no assurance it is being enforced. The Food and Drug Administration does not have adequate personnel to check grain crossing state lines, nor do they make such an attempt. Therefore, toxin-tainted corn can move freely in interstate commerce without ever being detected.

Since the advent of tests like ours, there has been a big step-up in the amount of testing for this carcinogen by many reputable firms and several state Deparments of Agriculture. However, the vast majority of corn is still untested. As an example, corn exported from the U.S. is tested only if the foreign buyer requests such a test be performed by the U.S. Department of

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Agriculture. Most foreign purchasers are not, as yet, requesting such. No governmental agency is at fault since none is charged with this responsibility.

Confusion Widespread

As you point out in your article, the Food and Drug Administration did relax standards on the legal limits of aflatoxin this past year. Of course, there is no indication that the human body has become more tolerant to the cancer-causing toxin just because the nation was faced with a drought. The new standards for this year allow for corn to move in interstate commerce at up to 300 parts per billion (this is 15 times the 20 part per billion level considered safe last year) if that corn was destined to specific uses. However, when a grain elevator receives corn, or for that matter when it is shipped, there is no way for them to know what the final usage of that product might be. If it is going to be used for human consumption or milk producing animals, it should not exceed 20 parts per billion according to the FDA regulation. On the other hand, if corn is to be fed to feed lot cattle, it can contain as much as 300 parts per billion. Since the farmer and grain elevator usually have no idea of the final destination of the product, the change in the FDA regulation has, in fact, made the situation even more confusing.

Your article points out that some corn - including popcorn - is not a problem. This statement is totally erroneous. We have two customers who are among the nation's largest producers of popcorn. One has found, and therefore refused to use, several lots of popcorn containing aflatoxin. Another reported an entire field of popcorn contained the toxin and therefore, did not harvest. Your article points out that many people are not concerned because they are using the "uncontaminated 1987 harvest." Again, this is unknown. The typical buyer of corn has no way of knowing what year the crop was harvested. In fact, 1987 corn that has been in storage for a year and a half at this point, is probably of lower quality and likely would be used for animal feed rather than for human consumption.

Equally erroneous is the comment that aflatoxin may not survive processing, and can be significantly reduced by cooking. Reams of research show aflatoxin to be highly stable, and existing in grain supplies for years. It cannot be destroyed by processing, eating, cooking, freezing, etc. The only documented method for detoxifying grain from aflatoxin is through a process using ammonia. Though this can be used to detoxify animal feeds, it is highly undesirable for human foodstuffs, and is almost never done.

I appreciate your giving me the opportunity to comment on your recent article. It is not our desire to create panic among consumers, but

it is important to clear up the confusion among handlers and processors in order to make sure we are doing all possible to provide a safe food supply.

Cordially,

James L. Herbert
President

JLH:dak

cc: Congressman Dan Glickman
Karen Springen - Newsweek

(c3)
Feb 23 '89

# Fungus in Corn Crop, A Potent Carcinogen, Invades Food Supplies

## Regulators Fail to Stop Sales Of Last Fall's Harvest Laden With Aflatoxin

## How a Trucker Passes Tests

By Scott Kilman
*Staff Reporter of* The Wall Street Journal

OQUAWKA, Ill. – From the corn fields that stretch for hundreds of miles around this Mississippi River town, one of the most potent cancer-causing agents known to science is coursing into the nation's food supply.

The corn in Charles Wayne's towering grain elevator goes everywhere from dairy farms in the county to Japanese food processors. And he has evidence that it is contaminated with aflatoxin. To impress a visitor, Mr. Wayne's son plugs in a lamp and examines under ultraviolet light samples of newly harvested corn his father bought from local farmers. Tainted grain usually will appear fluorescent.

Sure enough, these golden-yellow kernels take on a greenish luminescence. They glow," says the younger Mr. Wayne, offering them as souvenirs.

Last summer's drought created hospitable conditions in the Midwest for the heat-loving fungus *Aspergillus flavus*. It produces aflatoxin, a substance that is 100 times more likely to induce cancer than the industrial pollutant polychlorinated biphenyl, or PCB.

### Cancer on a Tiny Dose

Laboratory rats develop liver cancer after 68 weeks on a daily dose of a few millionths of a gram – the same diet of aflatoxin ingested by people in regions of Asia and Africa that have the world's highest incidence of liver cancer.

Because it occurs in nature, aflatoxin can't be controlled by merely closing a factory somewhere. And the Midwest, which is the source of roughly one-third of the world's corn, is the worst conceivable place for an outbreak: One-third of the official samples from the 1988 crop tested in Iowa and Illinois have been found to contain dangerous levels of aflatoxin. Five other Corn Belt states also report contamination. Tens of millions of bushels of corn harvested last fall were tainted, and the infection can spread while corn is stored in elevators. Certain grain terminals and food companies are finding aflatoxin in 20% of the corn they are buying from Midwest farmers.

Mr. Wayne and his son don't seem to care, but they are also endangering their own lives by breathing the corn dust they have all over their clothes, all over their office. They risk lung disease merely by being around aflatoxin.

The scope of the peril is broader still. Contaminated corn is being fed to dairy cattle, which pass aflatoxin on in their milk. In Texas, about two million pounds of tainted milk has had to be dumped. And the poison is finding its way into breakfast cereals, cornmeal, tortilla chips and other processed foods. The average American each year consumes about 160 pounds of corn and corn products.

While no deaths or cases of cancer have been traced to aflatoxin unleashed by last year's drought – cancer can take years to develop – aflatoxin is a threat to the food supply and the public health. "There's no way to escape it," says Rodney E. Leonard, the executive director of Community Nutrition Institute, a Washington food safety advocacy group. "Ten to 20 years from now, there will be more cancers because of this."

- Milk and cheese
- Corn meal (in bakery products, corn chips, cookies, corn muffins, corn bread and other snack foods)
- Hominy
- Breakfast cereals
- Grits
- Tacos
- Corn bran (in bread and health foods)
- Liver and kidneys (beef, pork and poultry)

In developing nations, Mexico for example, where imported U.S. corn is an important part of the diet, the danger is far greater.

Regulatory efforts to stop the spread of tainted grain, inadequate at best, have largely failed. The Food and Drug Administration restricts the interstate shipment of corn containing more than minuscule amounts of aflatoxin. But surveillance is spotty and prosecutions rare.

Federal and state regulators are hobbled by a lack of manpower and, in some cases, by a conflict of interest. Strict enforcement would cut into the nation's food supply and endanger the economies of farm states, regulators say. And so, the food industry is left for the most part to police itself.

The people who buy the corn – it is up to them to protect themselves," says Odette Shotwell, the Agriculture Department's top aflatoxin researcher. "We have to depend on the absolute fear of being caught selling a carcinogen."

Regulators and industry officials are taking the position that consumers have little to fear. Their argument is that contami-

*Please Turn to Page A8, Column 1*

# Spreading Poison: Aflatoxin Fungus

*Continued From Page A1*

nated corn will be diluted by the billions of bushels of clean corn that was also harvested. They also note that farm animals can be fed a certain amount of contaminated corn without showing a residue in their meat. What's more, aflatoxin-related disease hasn't heretofore been identified as a problem, and the U.S. has a relatively low rate of liver cancer.

People have taken steps to deal with aflatoxin, says Ronald Phillips, a spokesman for the U.S. Feed Grains Council, a Washington group of merchants, processors and producers. The actual incidence of contamination hasn't turned out to be nearly as bad as feared.

Yet FDA officials grudgingly admit that more could be done to enforce existing rules. "I do think we have a good program," says John R. Wessel, the director of the FDA's contaminants policy staff. "I would have to agree that federal controls and certain state controls could be improved."

A five-month investigation by this newspaper into the grain trade in the heartland shows widespread ignorance and disregard for the hazards, to workers as well as consumers. Many farmers and grain elevators are trafficking freely in untested corn. Others who make an effort to test for aflatoxin use procedures so flawed or sloppy that contaminated corn slips into commercial channels anyway. Testing by many food companies, dairy farmers and livestock raisers is random at best.

### Missing the Bus

The chances of being caught violating FDA rules are slim, and the corn can make it to market no matter what. In one case, a reporter witnessed an FDA investigator sample a truckload of corn at a major grain elevator and send the sample off by Greyhound bus to a government laboratory. By the time the test results came back weeks later, showing five times the aflatoxin considered safe for human consumption, the grain had long since been shipped down the Mississippi River and sent overseas.

Neither the government nor the industry is capable of dealing with the aflatoxin outbreak, says David Wilson, a University of Georgia professor of plant pathology. Adds James P. Minyard, state chemist for Mississippi: "There is just no way of policing a massive system of commerce and trade."

As the dangerous 1988 harvest moves into world food and feed supplies, the farmers, middlemen and food companies that process and deliver it to consumers in the U.S. and throughout the world face an impossible conflict of interest.

## THE FARMER

Martin Yoder strides across the barren yard of his 260-acre Wellman, Iowa, farm and climbs to the top of a 40-foot steel bin in a freezing wind. Wriggling through a tiny hole in the roof, he drops 15 feet with a thud into 3,200 bushels of aflatoxin contaminated corn – the fruit of a year's labor.

It looks perfectly fine to me, but I wouldn't eat it," the 32-year-old farmer tells a visitor, his voice muffled by a paper mask of the sort he has begun wearing when he is around the bin. "I don't even want to breathe it," he says.

The fungus that produces aflatoxin crept like a thief through Mr. Yoder's small farm last summer. Unlike most of the fungi that live in the soil, Aspergillus flavus thrived in 1988, as the farm got half the normal rainfall and experienced twice the usual number of 90-degree days.

By August, the leaves shielding the ears of corn had shriveled. Kernels cracked in the heat and exposed their starch to windblown spores of fungus. As the fuzzy brownish green mold ate deep into the kernels, it excreted aflatoxin.

There was little warning, and no way to prevent it. The mold is hard to see. And the first crop that was harvested in the county – sweet corn – didn't set off alarms. The corn in the cob sold at roadside stands and the canned and frozen corn sold in supermarkets are rarely infected. That crop is harvested well before the sugar in kernels has been converted to the starch that Aspergillus flavus thrives on. Sweet corn is a minor part of the U.S. crop. Field corn is harvested in the fall when it is dry, and that is where the aflatoxin problem mainly lies. About 60% of the field-corn crop is fed to animals, while the rest goes into products ranging from beer to baked goods.

Until he tried to sell his harvest, Mr. Yoder's main concern was whether the drought-damaged crop would yield enough grain for him to make his payments on the farm loans he renegotiated last year. But aflatoxin test results on his corn gave him something new to worry about.

### Lighting the Light

His corn lit up under black light at a local elevator. And Mr. Yoder was on hand to witness the subsequent chemical analysis showing that his corn contained five times the aflatoxin the FDA sees as safe for human consumption. "Bingo," said the worker, Mr. Yoder recalls. "It put a knot in my stomach."

With a crop that might have brought about $8,500 rejected by the local elevator, Mr. Yoder is once again in danger of losing his farm. Without the revenue from his corn, he may not be able to meet loan payments next summer to the Farmers Home Administration. "I'd be lying if I said I'm not thinking about quitting," he says. "We finally got matters settled with the banks, then this happens."

He is commendably reluctant to sell the contaminated grain to livestock raisers for feed. "I worry about pushing it into the food chain," Mr. Yoder says. "My corn could go into a lot of bacon and eggs."

For now, he is waiting, although he isn't sure for what. "It's as good to me as counterfeit money now," he says, letting a handful of the golden kernels drain between his fingers.

### Bad Surprise

For a conscientious man like Mr. Yoder, aflatoxin contamination is a devastating surprise. Few Midwest farmers and grain merchants know much about the contaminant. A lot of corn around here was similarly poisoned during a 1983 drought. But sales weren't much affected because the tests that are available now hadn't come on the market.

Tests aside, two decades of research have yielded no way to prevent outbreaks of aflatoxin contamination, no hybrid varieties of corn resistant to the fungus, no safe way to rid crops of the blight. Medical science hasn't made all that much progress, either. Some researchers aren't convinced by animal tests that aflatoxin is a potent cancer causer. The best evidence that it is dangerous comes from rats; monkeys and mice, however, are resistant. Moreover, liver cancer is prevalent in primates where

## The Aflatoxin Peril Unfolds

**Summer** The Midwest drought ignites the spread of *Aspergillus flavus*, a soil mold that produces the carcinogen aflatoxin.

**SEPTEMBER**

**Early September** The corn harvest begins, and a river of grain begins flowing to food and feed mills in the U.S. and overseas.

**Mid-September** Federal grain inspectors in the port of Baltimore detect aflatoxin in U.S. corn. In Texas, several grain elevators are ordered not to sell their contaminated corn, and about 20 dairies dump aflatoxin-tainted milk. In the Midwest, where the harvest is one-fourth complete, government inspectors discover aflatoxin in corn samples in Iowa, Oklahoma and Indiana.

**Sept. 27** Crop and milk contamination is confirmed in Minnesota. Farmers and merchants flood testing laboratories with thousands of samples.

**Sept. 28** Illinois, South Dakota and Maryland officials confirm the presence of aflatoxin. Contamination fears snarl grain trading.

**OCTOBER**

**Week of Oct. 3** The Food and Drug Administration eases aflatoxin limits on corn in interstate commerce to avoid disrupting the harvest. Wisconsin detects aflatoxin in its corn harvest. Illinois announces that 35.8% of corn samples it collected has more than 20 parts of aflatoxin per billion. Several food companies expand testing, although the harvest is already one-third complete.

Some Mississippi River grain terminals in the Midwest begin flagging aflatoxin in 20% of the corn they test. North Dakota tests grain for contamination. A vessel in New Orleans unloads a shipment of corn after aflatoxin is detected. Some importers begin requiring aflatoxin testing of all U.S. corn.

**Oct. 14** Iowa State University researchers report aflatoxin in 36% of corn sampled by elevators in the leading corn-producing state, wiping out hope of containing the problem.

**Late October** An Illinois dairy dumps contaminated milk.

**NOVEMBER**

The corn harvest ends. In Iowa, traces of aflatoxin are found in cartons of milk, and several dairies dump milk. Contaminated milk is found in Wisconsin.

**DECEMBER**

Dairies in Minnesota and Florida dump contaminated milk.

**THEREAFTER**

The 4.93-billion-bushel U.S. crop continues to move into interstate and world trade.

flatoxin is rife, but so is hepatitis, and researchers have trouble weighing the variables. Scientists recently have devised a quick way to measure aflatoxin in blood and urine, but tests aren't generally available.

The International Agency for Research on Cancer, a part of the World Health Organization, regards aflatoxin as a carcinogen in human beings. Based on animal cancer tests, the substance obviously can't be given to human subjects; the FDA considers grain unfit for human consumption if it contains more than 20 parts of aflatoxin per billion. Which means that a quantity of aflatoxin weighing no more than a single kernel of corn—0.3 gram—is enough to contaminate 625 bushels.

And aflatoxin isn't just the seed of cancer cases that will be diagnosed 20 or 30 years from now. It is poisonous. Incidents of acute illness and death aren't unheard of. A fatal dose of the stuff can be measured in milligrams. In 1974, according to medical journals, nearly 1,000 villagers in western India became sick—and about 100 people died—after eating aflatoxin-tainted corn. In the early 1980s, 20 Kenyans were hospitalized and 12 died from ingesting contaminated grain.

### Shunning Moldy Corn

The likelihood of poisonings in the U.S. is remote, health authorities say, because to get sick one has to eat corn that is obviously moldy, and only a desperately hungry person would do that.

But aflatoxin as a genuine occupational hazard. More than a decade ago, a Czechoslovak chemical engineer who had been working in a laboratory on a method to remove aflatoxin from livestock feed died a year after the project was finished. An autopsy found lung tissue that glowed under black light examination.

The farmers who drove combines through dry fields during last fall's harvest kicked up huge clouds of dust, which can carry aflatoxin and the Aspergillus flavus fungus. And workers from grain elevator to cereal factory were exposed to corn dust. In many places, nothing is done to monitor conditions.

The danger to consumers is less clear. The carcinogen was discovered more than 20 years ago in the Southern peanut crop. But public health authorities have no record of aflatoxin-related fatalities in the U.S. And it is far from certain that aflatoxin deaths would be correctly diagnosed. "Many doctors aren't aware" of aflatoxin, says Garnett E. Wood, an FDA research chemist.

No wonder, then, that corn merchants blink at the rules.

## THE MERCHANT

For Charles Wayne, a stocky, likable elevator owner with a furrowed brow, change has been slow in coming. Mr. Wayne has been buying and selling grain for 50 years here in Oquawka, a town of 1,500 people. Before the Mississippi froze in December, he sent five barges of newly harvested corn downriver to New Orleans, where most of America's $4.3 billion in annual corn exports are shipped overseas.

There is aflatoxin here. Local elevators are rejecting corn because of contamination. Farms for hundreds of miles around are affected. Mr. Wayne didn't begin sending corn to a laboratory for testing until the harvest was nearly over, even though he knew from his son's impromptu black-light demonstration earlier in the fall that some of what he had sold probably harbored the deadly substance.

As far as he was concerned, the risk of alienating customers far outweighed any health risks. "I have to deal with farmers every season," he says. "I don't want to lose customers." Besides, exporters in New Orleans are counting on Mr. Wayne to deliver grain. The drought of 1988 has made corn scarce.

"Things are going to be tight," Mr. Wayne says, as he looks out the window at the tugboat Miss Kelly, which awaits a load of corn.

If one of his customers downriver should find aflatoxin, a shipment could be rejected, and Mr. Wayne would be stuck with the grain and the costs of transporting it.

But his sales have come off without a hitch. While testing done by exporters at the Gulf is as rigorous as any in the country, procedures there too are sometimes sloppy. The Agriculture Department's grain-inspection arm, the Federal Grain Inspection Service, doesn't even consider aflatoxin content in grading corn bound for overseas buyers. A federal test for aflatoxin requires a special request. U.S. officials assume that most export corn is fed to livestock, but buyers abroad don't say what their intentions are, and some of the corn they buy may well end up in people's stomachs.

## THE TRUCKER

Few know more about the regulatory safety net and its deficiencies than trucker Lyle McQuillen. Mr. McQuillen hauls corn to elevators for farmers around Bennett, Iowa.

Many of his sales last fall were to river terminals like the towering Pillsbury Co. grain facility near Davenport, 60 miles up the Mississippi from Mr. Wayne's elevator. The elevator, which was sold in December to ConAgra Inc. of Omaha, is one of many huge elevators that send grain to New Orleans, and late last year some were rejecting one of every five trucks, because of aflatoxin. Mr. McQuillen grins as a Pillsbury employee climbs up the side of his truck and jams a hollow six-foot rod into the load of newly harvested corn.

Mr. McQuillen has had his share of rejections. As he watches the Pillsbury employee, he mentions that the terminal recently turned away one of his truckloads.

If Mr. McQuillen doesn't find a buyer for the loads he hauls, he doesn't get paid. But he has always found somebody who will take [redacted] off his hands sooner or later. After Pillsbury rejected the earlier shipment, he says, he took it to a second elevator that similarly tested and rejected it. But the third terminal he tried, one operated by a major grain-export concern, tested the grain and accepted it as clean, he says.

Mr. McQuillen is contemptuous of the tests, which he dismisses with an obscenity. "I've gotten everything through," he boasts. He doesn't feel particularly guilt-ridden, because he doesn't think the tests are accurate.

To researchers familiar with aflatoxin, Mr. McQuillen's success would come as no surprise. The detection of such infinitesimal amounts of aflatoxin as 20 parts per billion is difficult even in ideal laboratory conditions. And the tests can be fooled.

Many buyers test for aflatoxin by scooping the top of the truckload with a coffee can; so a trucker can evade detection by covering contaminated grain with a layer of corn he knows is clean. Even repeated deep probing can miss contamination.

### All That Glitters

A black light test isn't reliable, anyway. Ultraviolet light merely indicates the presence of a fluorescent mold, of which aflatoxin is but one. So the test isn't conclusive. What's more, Aspergillus flavus doesn't always glow, according to plant scientists and food-company research.

## How Aflatoxin Invades the Corn Plant . . . and Where the Crop Goes

② The spores often enter through the crown. Once inside, the fungus proliferates during the silking process where the moist environment helps it to grow. The plant, already weakened by the drought, falls victim and becomes further infected.

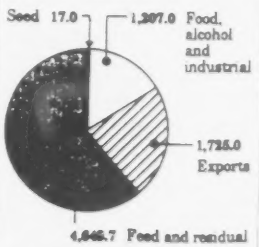
③ As the kernel reaches maturity, the fungus moves through the base of the grain and branches into the embryo in the form of hair-like mycelia. The largest accumulation of toxin occurs during this stage. Following the harvest, mycelia can continue growing in damp and unaerated storage bins.

① Under extremely dry conditions like the Midwest experienced last summer, with day-time highs of about 100 degrees and evenings in the upper 70s, the soil-borne fungus (Aspergillus flavus) becomes dust-like and airborne.

Source: Iowa State University

### Supply and distribution for crop year 1987-1988*

(In millions of bushels)




*Preliminary figures, September 1987 - August 1988

Source: U.S. Department of Agriculture

Another widely used field test, the EZ Screen test made by Environmental Diagnostics Inc. of Burlington, N.C., gave too many wrong results to win approval in 1986 from the Association of Official Analytical Chemists, which validates lab procedures. Environmental Diagnostics says it may ask the association to reconsider. But even if the EZ Screen test is eventually approved, there's no guarantee it would be reliable in the hands of an elevator worker. Rita Bahner, the assistant executive director of the chemists' association, says that, to be accurate, chemical tests must be conducted by a competent scientist under laboratory conditions.

Laboratory conditions customarily involve precautions to ensure accuracy and to protect the safety of workers who do the testing. In Cedar Rapids, at Sanslabs, which conducted hundreds of aflatoxin tests last fall, workers in safety glasses, protective gloves and masks seal grain in plastic, then grind and analyze it.

Most grain merchants, on the other hand, treat aflatoxin as if it were harmless. Samples are handled casually, and workers freely breathe contaminated grain dust.

## THE ELEVATOR WORKER

Procedures at Continental Grain Co.'s terminal on the Mississippi River at Muscatine, Iowa, are as good as any in the industry. In an unheated room at the base of the elevator, dust from grinding grain samples hangs in the air as J.D. King, the gruff, barrel-chested elevator superintendent, peers into a small black box. "We got sparkplers," he announces.

The driver of the truck sitting outside watches impassively as Mr. King sticks a finger through the side of the box and stirs the corn. Bathed in the purple light of an ultraviolet lamp, five kernels glow like fireflies.

Mr. King carries the suspect corn to a makeshift laboratory in the employee lunchroom. By a sink cluttered with coffee cups, he mixes the powder in a plastic container with clear liquid solvent, whirs it in a Hamilton Beach blender, then drains the concoction through a coffee filter into a Styrofoam cup.

Across the table, the trucker in overalls works on a bag of potato chips as Mr. King rips open a packet containing an EZ Screen test. He spills the contents onto the table: a red, a green and a blue dropper, and several clear tubes.

Biting his lip, Mr. King swears as he mixes and shakes the tiny plastic devices, then squeezes two drops onto a piece of paper the size of a playing card. Mr. King studies it for several minutes, watching for a color change, then tosses the card across the table. "Positive," he announces. The driver's face reddens, and he lumbers back to his truck. The next two trucks that pull in are also rejected. In frustration, Mr. King slams the lunchroom table.

Like others in the business, Continental doesn't report the results of positive aflatoxin tests to other elevators or to the FDA; it just tells the driver. The result: Truckers intent on selling contaminated corn can usually find a buyer if they persist. And the FDA's scattered regional inspectors are faced with the impossible task of turning back a tide of bad corn.

## THE REGULATOR

From a dozen massive elevators along the 150 miles of river front between Dubuque and Burlington, Iowa, gushes much of the state's corn for export.

It's John Iwen's job to test it.

In a good week, the 42-year-old FDA investigator, armed with a briefcase and a long probe, collects about 90 pounds of the more than 200 million pounds of corn that move through the terminals downriver. Millions of bushels of newly harvested corn were shipped to New Orleans from contaminated regions last fall, *before* Mr. Iwen got orders from his St. Louis headquarters to start taking samples.

Mr. Iwen eases his white government car through a muddy parking lot at the Pillsbury terminal near Davenport and scans the scene. Two trucks are waiting to unload their corn into the grain elevator, where it is quickly piped onto waiting barges.

A stout man stuffed into a red plaid shirt, jeans and work boots, Mr. Iwen collects his probe and his briefcase and walks unannounced into the elevator's office.

He is expected. Forest Storm, operations manager for the Pillsbury terminal, says truckers told him that an FDA investigator took samples at a nearby terminal the day before.

### Visit to Pillsbury

Mr. Iwen sits at an empty desk with his feet on his briefcase as Mr. Storm calls Pillsbury's Minneapolis headquarters for clearance. Twenty minutes later, with Mr. Storm at his side, Mr. Iwen walks outside to a silver truck from which a Pillsbury employee has just taken a sample.

Mr. Iwen climbs a ladder and gingerly steps on top, sinking to his knees in the corn. He jams the tip of the six-foot probe into the corn, then throws his weight against it. Twisting a wooden knob at the top of the probe, he locks in the corn that has fallen into openings along the side of the rod. He yanks out the probe and dumps the contents onto a white cloth. Sweat beads on Mr. Iwen's forehead and he sheds his jacket. Sixteen thrusts of the probe produce 10 pounds of corn, which he wraps in a grocery sack.

He will send the sample by bus to a Kansas City laboratory, which has been finding unsafe levels of aflatoxin in one-third of his samples. Two weeks later, the results will come back. The grain is contaminated with 103 parts of aflatoxin per billion, more than five times Pillsbury's own limit.

When Mr. Iwen filled out a receipt for the corn he took, Pillsbury finished its own testing and approved the load he had sampled. The silver truck pulled away, the corn destined to go downriver by barge for shipment overseas.

### Down the Mississippi

Mr. Iwen contacted Pillsbury when the government test results came back and was given the identification numbers for two barges that may have carried the bad corn down the Mississippi. The company wouldn't provide any further information, according to FDA documents describing the incident. Mr. Iwen gave the barge numbers to his superiors, but FDA inspectors in New Orleans weren't notified, and no effort was made to track down the barges.

Pillsbury disputes the accuracy of the FDA test. "We tested it twice, and both tests were negative," a company spokesman says.

Besides, Pillsbury isn't obliged to hold corn pending the results of Mr. Iwen's tests. And even when Pillsbury itself rejects a load, it doesn't have to tell anybody about it. Mr. Storm laughs when asked if he knows what becomes of the corn Pillsbury rejects. "I don't want to know," he says. "I'm not going to call John Iwen!"

The federal penalty for transporting adulterated food across a state line is a maximum of three years in prison and a $250,000 fine for each shipment. But criminal convictions involving aflatoxin are rare; it isn't clear how much is too much to be legal. The FDA hasn't gone through the public rule-making process of setting a tolerance level for aflatoxin in food.

To guide its investigators, the FDA has established levels at which it might be willing to take an aflatoxin case to court. But in previous aflatoxin outbreaks, the agency has indulged higher levels in food.

Until last fall, the FDA considered more than 20 parts per billion in corn to be sufficient for legal action. But in October, the FDA said it would allow up to 100 parts per billion in livestock feed. "The FDA pushes it aside," says Mr. Leonard the food advocate and critic of the agency, referring to the abandoned standard, "and pretends it doesn't exist." The FDA kept the lower limit for corn consumed by people and by dairy cattle. Its strictest limit is for aflatoxin in milk: 0.5 parts per billion.

The FDA says that as a practical matter it can't regulate aflatoxin in food as strictly as it does much less potent carcinogens because it could mean destroying a crop that keeps people alive in much of the world.

The problem is that there is no way to have a corn supply that is absolutely free of aflatoxin, says L. Robert Lake, the director of compliance for the FDA's Center for Food Safety and Applied Nutrition. The question is how much to put up with.

During aflatoxin outbreaks, the FDA has to rely on manpower from states, most of which have adopted the agency's aflatoxin guidelines. But many farm state regulators feel powerless. State chemists and university scientists in Iowa, Illinois and Indiana have conducted grain surveys, and officials in many other states have found aflatoxin. But little has been done to police the trade in tainted grain.

### Hot Potato

For farm state officials, aflatoxin is a political issue they are reluctant to take on. Corn, after all, is one of the most important products in Iowa, Illinois and Indiana.

If those who regulate grain elevators lack money and manpower, they also seem to lack the will. "We aren't going to look for aflatoxin," says Donna Gwinn, the director of Iowa's elevator-regulation bureau. "You can't shut them all down."

Many state officials don't want the fact out that it isn't clean corn, says Nadine Drennan, the manager of a private Cedar Rapids laboratory that was flooded last fall with requests from farmers and food companies for aflatoxin tests. "I've been appalled at regulators' laissez-faire attitude," she says.

Federal grain inspectors have no responsibility for halting traffic in contaminated grain. And employees of the Agriculture Department test domestic shipments and those headed overseas only on request. If they find dangerous contamination, they aren't responsible for tracing the shipment to its source, says Jim Bair, assistant to the administrator of the Federal Grain Inspection Service.

Although the FGIS tests hundreds of samples sent to it by grain dealers and farmers, it informs the FDA only if it finds aflatoxin in a sample collected by one of its own employees. Thus, while roughly half the 1,558 aflatoxin tests conducted by the FGIS by mid-November showed dangerous levels of contamination, results of fewer than 30 tests were given to the FDA.

### Stricter Standards

Some importing nations, notably Japan and the Soviet Union, that set stricter limits on aflatoxin than the U.S. does are nervous. An FGIS official says a couple of ships have had to unload corn at U.S. ports because they were rejected by a foreign buyer.

Japanese importers are demanding that everything from sweet corn to corn chips either be tested for aflatoxin or carry certification that it was made from the '87 crop. U.S. shipments have sat in Japanese docks for weeks while U.S. exporters scrambled to get together the obligatory paper work.

Frank Schy, the owner of Mexi Snax Inc., in Hayward, Calif., says a Japanese trading firm canceled an order for his blue corn chips because of the aflatoxin scare. The Japanese wanted a certificate giving the product a clean bill of health, but Mr. Schy says he has never tested for aflatoxin.

Small wonder, then, that aflatoxin has begun to show up in alarming amounts in milk, in livestock feed and in stockpiled corn destined to be used in processed foods.

## THE DAIRYMAN

Charles A. Sides thought he was doing everything humanly possible to avoid the aflatoxin problem.

The Canton, Texas, milk producer had bought corn from an elevator that certified it as aflatoxin free. Then, he had a private laboratory test it and pronounce it clean.

Within days of feeding it to his cattle, however, his local cooperative found dangerous levels of aflatoxin in the milk they produced. As a result, Mr. Sides had to dump 100,000 pounds of contaminated milk; nobody would buy it. He estimates he lost six days' work because of the tainted feed, which subsequent testing showed contained 335 parts of aflatoxin per billion – almost 17 times the FDA limit for dairy cattle feed.

Mr. Sides's problem isn't unique to him. Milk is the one product that many states are scrambling to test. Farms in Iowa, Illinois and Minnesota have had to dump milk, and traces of aflatoxin have been found in the milk of several Wisconsin dairy farms.

Milk is particularly susceptible to contamination, but aflatoxin is also a threat to corn meal, corn chips, tortillas, breakfast cereal and other processed foods. State and federal regulators say they depend on food companies to screen the grain they use.

But of a dozen food companies big and small contacted by The Wall Street Journal, several were reluctant to discuss their procedures. The manager of a Chicago-based tortilla maker had never heard of aflatoxin. The president of a California exporter says he assures Japanese customers that his products are made from the 1987 corn crop, even though they are actually made from the 1988 crop.

And several, including General Mills Inc., say they depend on the millers that supply them to certify that grain is aflatoxin free. General Mills does do its own random testing to check up on millers. The Minneapolis company didn't begin requiring suppliers to test every load of corn until last October, well after the harvest had begun.

## THE FOOD COMPANY

But Quaker Oats Co. knows that depending on suppliers to test for aflatoxin doesn't do the trick. At the world's largest cereal mill, Quaker Oats in Cedar Rapids, Iowa, goes to extraordinary lengths to stop aflatoxin from creeping into its breakfast cereal, corn meal and other foodstuffs.

"It's the most serious thing we look for" in testing grain, says Kenneth L. Dykes, the plant manager.

Last fall, Quaker found dangerous levels of aflatoxin in roughly 20% of the corn received – 20 times as much as usual. "I don't think farmers and elevators do screen for aflatoxin," Mr. Dykes says.

The procedure is costly. Outside the Quaker mill, trucks full of corn are driven beneath a yellow robotic probe that looks like a giant mosquito. It jabs each truck in nine spots to different depths.

Samples are taken to a plant laboratory, where two goggled and gloved technicians are employed full time, year round to grind and mix samples into a solution and inject it into tiny tubes. In a darkroom, technicians study the intensity of a glowing blue ring on the inside of each tube to determine whether the sample exceeds the company limit of 15 parts of aflatoxin per billion – a standard 25% more exacting than the FDA's.

### Repeated Testing

Corn is tested again each time it is moved within the mill, as many as six times all told. Then, randomly selected boxes of everything from corn meal to Cap'n Crunch breakfast cereal are tested before leaving the mill.

Truckers wait in a holding area for up to five hours for test results. Last fall, tempers flared as truckload after truckload was rejected; the company began to use security guards to break bad news.

Such findings worry some scientists familiar with aflatoxin, who say things could get still worse. Much of 1988's drought-ravaged harvest is still in storage. Recent research shows that aflatoxin can increase ten-fold in just three days in improperly dried grain.

"By the time the corn comes out [of elevators] next spring, it will be at the 1,200- to 1,500-parts-per-billion level," predicts Mr. Maynard, Mississippi's state chemist.

By then, drought-ravaged corn supplies will be tighter and prices higher, which increases the incentive ranchers and merchants have to violate FDA limits and traffic in contaminated corn. And as for the size of the 1988 harvest, it's too early to make predictions.

## THE SPECULATOR

Hidden in every catastrophe lies a golden opportunity to make money.

Or so believes Charles Cassens, who owns a big elevator in aflatoxin-ridden Keokuk County, Iowa. He is trying to corner the market in contaminated corn.

Among merchants, Mr. Cassens is a prophet of doom. The drought reduced the corn harvest in his region by three-fourths, and much of the grain that remained was tainted. As time goes on, Mr. Cassens reasons, those who raise livestock will grow desperate for any kind of corn, contaminated or not, to feed their animals.

Thus, last fall he was snapping up corn containing as much as 1,300 parts of aflatoxin per billion – which is four times the FDA's limit for cattle feed. The FDA limits aflatoxin in feed to 300 parts per billion for cattle nearing slaughter, 200 parts per billion for mature hogs, 100 parts per billion for breeding livestock, and 20 parts per billion for dairy animals.

The agency prohibits blending contaminated grain with clean corn for use as feed unless it is done under federal or state supervision. According to Iowa authorities, no one in the state has applied for permission to blend contaminated corn.

But some of Mr. Cassens's customers use his highly contaminated corn to feed animals that eventually will be slaughtered and sold as meat. "I can't legally do it [blend tainted grain into feed]," he says. "So I leave it up to him [the rancher] to decide."

Despite the FDA standards, many ranchers don't test their feed at all. Gilbert Gingerich, a Parnell, Iowa, cattleman, says he was forced to buy contaminated corn for his animals after his own crop was wiped out by the drought. (He doesn't test the grain he feeds them, he says, because he doesn't believe the corn is bad enough to hurt his animals.)

Meatpackers don't test their products for aflatoxin, either. IBP Inc., the nation's largest beef packer, confirms in response to questions that it doesn't test carcasses for aflatoxin. "We're not aware of any problem with aflatoxin in meat. We're not commenting beyond that," says an IBP spokesman.

### Perceptible Amounts

Meatpackers say livestock would get sick before aflatoxin residue started affecting their meat. "It is very difficult to get an animal to consume enough aflatoxin to get enough to show up in meat," said a spokesman for Geo. A. Hormel & Co., in Austin, Minn.

The fact that contaminated corn is being fed to livestock for slaughter scares some people. "I'm pregnant and I worry about it showing up in the residue of meat," says Rhonda Wehr, a Sigourney, Iowa, veterinarian. "I've read everything I can, but it seems no one really knows if it gets into meat."

Mr. Cassens, a few blocks away, says he can't afford qualms about supplying the industry with tainted corn. It is keeping him in business in a year when there is little else for him to sell. "There isn't any documented evidence that aflatoxin has ever hurt anyone," he insists.

Next to him, leaning on a sales counter, a mill hand adds: "We've got to feed something."

"THE WALL STREET JOURNAL"
WEDNESDAY, OCTOBER 5, 1988

# Tainted Corn Eased by U.S.

By BRUCE INGERSOLL
*Staff Reporter of* THE WALL STREET JOURNAL

WASHINGTON—The Food and Drug Administration relaxed its limits on the interstate shipment of aflatoxin-tainted corn amid growing evidence of widespread contamination of the 1988 corn crop.

The agency's new policy on aflatoxin, a fungus-produced poison that can kill livestock and is suspected of causing liver cancer in humans, should help to stave off bottlenecks in grain marketing in the Midwest and elsewhere.

As it did in the drought years of 1980 and 1983, the FDA will allow interstate shipments of corn containing as many as 100 parts of aflatoxin per billion if state officials can ensure that the corn will be fed only to mature beef cattle, hogs and poultry.

But in a break from previous policy, the agency said it will tolerate higher levels of aflatoxin in beef cattle and hogs in feed lots that are destined for slaughter. The new limit for finishing hogs weighing more than 100 pounds will be 200 parts per billion, and the new limit for finishing beef cattle will be 300 parts per billion.

The FDA will allow the blending of aflatoxin-adulterated corn with clean corn to produce a permissible mixture. But such blending must be done under the supervision of FDA or state officials.

The FDA said it is standing pat with its aflatoxin limit of 20 parts per billion for sweet corn and other food and for corn being fed to dairy cattle. The limit on corn destined for immature animals, including poultry, will be 20 parts per billion as well.

FDA officials also will continue to enforce a limit of 0.5 parts per billion for milk under the government's Interstate Milk Shippers program. If they detect excessive levels, they will track down the source of the dairy cattle feed.

The FDA, in setting levels in the range of 100 to 300, was guided by research on how well livestock stand short-term exposure to aflatoxin.

"At this range, only dairy cattle would pass the aflatoxin onto the consumer," said Elizabeth Campbell, chief of the FDA's guidelines and compliance research branch. "Before we would see potentially harmful levels in meat and eggs, we would have levels potentially harmful to the animals."

Research data indicate that "these levels wouldn't result in any aflatoxin residues in meat or eggs," she added.

A recent Court of Appeals decision found that the FDA's so-called action levels aren't binding on the courts, but the agency wasn't prohibited from using these levels as guidelines. The FDA, nonetheless, believes it still can justify seizing tainted corn if it exceeds the new limits.

Ms. Campbell noted that the FDA didn't set the new limits for only this year's crop, contrary to its policy in 1980 and 1983.

"The Wall Street Journal" Oct. 3, 1969 COMMODITIES

# Aflatoxin Outbreak Is a 'Double-Edged Sword' As Traders Are Uncertain on Corn-Price Outlook

By Scott Kilman
Staff Reporter of The Wall Street Journal

CHICAGO—Futures traders don't know which way to turn yet on the aflatoxin contamination of the Midwest corn crop.

Some see prices jumping if the outbreak further slices the supply of good quality corn available from the drought-stunted harvest. Others see prices faltering if the outbreak spooks importing countries, which consumed one-fourth of last year's U.S. corn harvest. Some big trade partners are tougher than the U.S. on aflatoxin, a fungus-produced poison that kills livestock, and is suspected of causing liver cancer in humans.

"It is a double-edged sword," says Patrick O'Connell, a senior grain analyst at Refco Inc., Chicago.

So far, the rare discovery of aflatoxin in the Midwest two weeks ago has only served to slow the normal drop in corn futures prices that comes as the harvest flows into hundreds of grain elevators, and they in turn sell futures contracts at the Chicago Board of Trade in order to hedge their purchases from farmers.

Any future price move depends on what traders can learn this week on the seriousness of the outbreak. More states might give details for the first time of the level of contamination found in grain elevators and cornfields. So far, aflatoxin has been detected by government inspectors in seven states, and is suspected in many more, but few states have a fix on the contamination's scope.

On Friday, Indiana officials said about 12% of 65 corn samples randomly collected around the state contained levels of aflatoxin considered dangerous to humans. Earlier, Illinois reported that one-third of the corn it tested was unfit for human consumption. In Texas, where aflatoxin rarely afflicts corn, state officials suspect that roughly one-fifth of the crop is contaminated.

Those findings were enough to spark speculation that elevators would disrupt the flow of grain across the country by rejecting farmers on the slightest suspicion of contamination. Many elevators are relying on a blacklight test to screen newly harvested corn. A glow under the blacklight is a common fingerprint of the fungus that makes aflatoxin, but it isn't an indication of whether the aflatoxin is present.

While the fungus is common in many parts of the country, it needs a climate such as is typical in the Southeast to manufacture aflatoxin. Toxicologists suspect the severe drought caused the rare Midwest outbreak.

To help stave off bottlenecks, the U.S. Food and Drug Administration is expected as early as today to relax its ban on the interstate shipment of corn that contains more than 20 parts of aflatoxin a billion. The agency is expected to allow corn used in some livestock feed, the crop's biggest use, to contain as much as 100 parts a billion, said Richard Loewy, senior grain and oilseed analyst at Prudential-Bache Securities Inc., New York.

The agency is expected to continue prohibiting the interstate shipment of corn containing more than 20 parts of aflatoxin a billion for use in human consumption and milk-producing livestock, he said.

Nonetheless, widespread contamination would disrupt the corn trade. A two-tier market between new and old corn might develop as what remains of last year's untainted harvest attracts an unusual premium. Disputes might erupt over what constitutes contractually required quality. The Chicago Board of Trade's definition of No. 2 corn, the industry standard, doesn't specifically ban aflatoxin.

No. 2 corn, the standard grade for export as well as domestic consumption, is based on density and cleanliness.

Some futures traders last week were pondering whether the Chicago Board of Trade might become a dumping ground for contaminated corn. Their short-lived theory was that someone stuck with a hot stockpile could get rid of it by selling futures contracts in the corn pit. That eventually requires the seller to deliver No. 2 corn at a Board-certified warehouse. If the warehouse couldn't reject the corn for aflatoxin, the seller's troubles were over.

In a statement released Friday, the Board said its warehouses can reject corn for aflatoxin contamination.

Nonetheless, aflatoxin is the sort of thing that will titillate traders for a long time. Many farmers don't screen the corn they store in their own bins. As a result, some state officials are worried that the aflatoxin-producing fungus will run rampant through farmer-owned storage—possibly making for new discoveries for many months.

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NY Times 3/5/89

(P.1)

**Fear of Aflatoxin**

# The Debate About The Carcinogens That Man Didn't Make

By WARREN E. LEARY

WASHINGTON

IN the war against chemicals that cause cancer, most of the attention has been on man-made substances like pesticides and preservatives. Increasingly, however, some scientists are arguing that the public has been infected with a bad case of chemophobia. Most cancers, they say, come from natural causes — the food, sunlight, plant poisons, tobacco and other things people encounter every day.

A case in point, they say, is aflatoxin, a carcinogen produced not by a factory but by a corn fungus. Last week scientists and Federal regulators debated whether the chemical had tainted the nation's food supply. At the same time, some environmentalists said that fears of natural carcinogens were being exploited by industry as a diversionary tactic. "They want to deflect attention away from their products or other synthetic chemicals to something we can't do much about," said Janet S. Hathaway of the Natural Resources Defense Council. "There is no one making natural carcinogens and no one to ask to stop."

The debate over the relative dangers of natural and synthetic carcinogens erupted in recent days when alarms were set off by two cancer-causing chemicals, one natural, the other man-made.

Aflatoxin is produced by Aspergillus flavus, a fungus that flourishes in hot, dry weather. Earlier this month The Wall Street Journal reported that unusually large amounts of aflatoxin were produced in corn supplies during last summer's drought. The chemical causes liver cancer in laboratory animals, but the Food and Drug Administration denied that enough of it had found its way into food supplies to pose serious risk.

Federal regulators seemed somewhat more concerned about a factory-made chemical called daminozide, sold under the brand-name Alar, which is used on about 5 percent of the nation's red apples to increase shelf life and enhance appearance. Last month, the Environmental Protection Agency said the chemical was carcinogenic and that it planned to ban it next year. But removing daminozide from the market is expected to take at least 18 months and could drag on for years if the decision is appealed by the maker or users.

Some scientists say that the painstaking process of regulating most synthetic carcinogens is not worth the trouble. "The big causes of cancer are clearly the natural ones, the hundreds or thousands of things people are exposed to every day," said Dr. Bruce N. Ames, a biochemist at the University of California at Berkeley, whose studies of natural carcinogens in food have fueled the debate over regulatory priorities. "We're making a big fuss about tiny traces of pesticides and other synthetic chemicals while 99.9 percent of the chemicals we are exposed to are natural and we pay almost no attention."

Ms. Hathaway of the Natural Resources Defense Council said that people should acknowledge that there are natural carcinogens like aflatoxin in food and radon gas in the soil that need regulation. But even if natural cancer-causing substances pose the biggest risk, she said, "the question is which risk is the thing we can do most about."

Dr. Ames counters that if the carcinogens that are most easily controlled account for only a small percentage of cancers, the Government is wasting resources and giving people a false impression that they are being protected. "There should be some relationship between the money spent and the hazard," he said.

Dr. Frederica Perera of the Columbia University School of Public Health said data are not available to estimate how much natural carcinogens contribute to the overall cancer burden. While people can avoid some natural carcinogens themselves — by stopping smoking or venting their basements of radon gas — there is little they can do about carcinogens produced by industry, she said. "We need to be aggressive with both kinds of carcinogens, but need sound regulation to control involuntary exposures," she said.

Dr. Ames noted that half the chemicals tested in animals, both natural and artificial, prove positive for causing some kind of cancer. These chemicals are administered at a level just below lethality in mice and rats, and he said it is wrong to use these high-dose, short-term results to predict the effect of minute-dose, long-term human exposure.

"Mice are not little men," said Dr. Elizabeth M. Whelan, executive director of the American Council on Science and Health, a New York research group that often supports industry positions on regulating chemicals. Pesticides have been used on foods for more than 50 years and no jump in cancer has been directly linked to them, she said, except possibly for some occupational exposures.

Both sides of the issue feel that the other is getting too much attention and basing its opinions on too little data. In the meantime, health experts worry that the public is developing the impression that everything causes cancer — an attitude that could impede measures to control the true hazards. But perhaps the common call for more research, better ways to determine human risks and more public education will make it easier for people to know what to believe when they hear about the next potential cancer hazard — natural or synthetic.

# FDA Finds Excessive Toxin in Some Corn But Says Consumers Shouldn't Worry

By Scott Kilman
Staff Reporter of The Wall Street Journal

The Food and Drug Administration confirmed the presence of unsafe levels of aflatoxin, a potent carcinogen, in 6% of the U.S. corn it sampled in recent months, but said consumers shouldn't be concerned about contamination of the food supply.

The agency issued a statement in response to a story in The Wall Street Journal last week about the poison produced by a fungus in last fall's Midwest corn crop.

Separately, agriculture department heads from three leading farm states and a major corn farmers group blasted the article as misleading. At the same time, Missouri became the fifth state to confirm that aflatoxin-contaminated milk had been dumped.

In its statement, the FDA said consumers are shielded from the carcinogen by its own testing, as well as screening by the U.S. Agriculture Department, state regulators and the food industry. The FDA said it "does not believe such concern about aflatoxin contamination of foods is warranted because there is plenty of aflatoxin-free corn available for human consumption, and several layers of protection are in place."

However, while the FDA statement was aimed at easing consumer fears about contamination of the food supply, it nevertheless left unanswered some questions about the effectiveness of screening for aflatoxin. Despite concerns on the part of some consumer groups, widespread screening of finished food products for the carcinogen hasn't been conducted.

The FDA disclosed, for instance, that a relatively small sampling by its inspectors had disclosed unsafe levels of aflatoxin in corn flour and cornmeal for human consumption, a sign that testing by farmers, merchants and processors had fallen short. The Journal story reported that many farmers and grain elevators traffic freely in contaminated corn and that regulatory surveillance is spotty.

The agency said six, or 2%, of the 263 samples of corn flour and corn meal it had collected contained more than 20 parts of aflatoxin per billion, the level the FDA deems unsafe for human consumption. Corn flour and meal are used in a wide range of baked goods. An FDA spokesman said he didn't know whether the tainted products had been removed from the market, as required by FDA policy, nor whether they were found in manufacturers' warehouses or on grocery store shelves.

And while the FDA also said that it hadn't found any trace of aflatoxin in samples of finished human food products such as cereal, tortillas, corn chips and popcorn, the agency said it has only conducted a small sampling of 100 items. An FDA spokesman said the small number of food samples collected so far isn't enough to determine whether aflatoxin is entering into these food products.

"The system seems to prevent aflatoxin from getting into finished products," the FDA spokesman said. "But we certainly want to continue" testing. Much of the 1988 corn harvest is still in storage, where aflatoxin contamination can worsen under certain conditions.

In its testing of unprocessed grain, the FDA said 105 of the 1,650 samples collected by inspectors since Oct. 1 in outbreak areas had more than 20 parts of aflatoxin per billion. It added that industry data from across the country show that less than 2% of 6,000 samples had more than 10 parts of aflatoxin per billion.

The FDA also confirmed that it hadn't found any aflatoxin in a survey of U.S. sweet corn it had conducted to ease concerns by Japanese importers. Sweet corn is rarely afflicted by aflatoxin.

Meanwhile, Missouri confirmed that a dairy in that state had to dump aflatoxin-contaminated milk last week. Although aflatoxin levels in the milk fell below the FDA's guideline of 0.5 part of aflatoxin per billion, it nevertheless was destroyed because it was destined for use in cheese, said Jim Kennedy, executive secretary of the Missouri State Milk Board. Processing milk into cheese can concentrate the poison.

Contaminated milk has already been dumped in Texas, Minnesota, Iowa and Illinois, the FDA said.

At a news conference in Nashville, Tenn., the National Corn Growers Association and the agriculture chiefs of Illinois, Iowa and Missouri charged that the Journal article made "serious and misleading statements."

Larry A. Werries, director of the Illinois Department of Agriculture, complained that the story implied that regulators and the corn industry either didn't recognize that there was a problem with aflatoxin or didn't care. "Just the opposite attitude is out there," he said.

Mr. Werries said the state is helping farmers test for aflatoxin. The state's Animal Disease Laboratory is conducting about 50 aflatoxin tests a day on samples for veterinarians, farmers and feed makers, among others.

Mr. Werries also said that all Illinois corn slated for export is vigorously tested, and that "unacceptable levels" of aflatoxin aren't being sent overseas. His comments were directed, in part, at a passage in the Journal story that cited the example of an Illinois grain terminal that ships corn for export down the Mississippi River. The terminal didn't begin to send samples to a laboratory for testing until the harvest was almost complete.

Missouri and Iowa officials also defended their states' handling of the outbreak. A representative of Nebraska said no aflatoxin had been found in any of that state's dairy herds.

Because of the volumes involved, many Midwest states are able to check only a fraction of their state's production of corn and milk. Illinois inspectors are collecting about a dozen milk samples a week. Iowa tests 10 different milk routes each week of the hundreds it has in the state.

Dale M. Cochran, Iowa's secretary of agriculture, said his department, which doesn't routinely monitor for aflatoxin, plans to continue testing milk until the 1988 corn crop is exhausted. "We can't test every bushel and gallon," he said, but added, "We feel good about our testing procedures."

@ NY Times 3/2/89

# Drought Sets Off Alarms on U.S. Response to Enemy of Corn

By WILLIAM ROBBINS
Special to The New York Times

KANSAS CITY, Mo., March 1 — The drought that laid siege to this country's grain crops last summer also set off alarms about another enemy of the food supply: the virulent poison aflatoxin that flourished on corn weakened by dry weather.

The threat of aflatoxin, which has caused liver cancer in laboratory animals, set in motion a system of inspections and spot checks intended to protect consumers.

Now a debate is under way in the food industry and among Government officials who regulate it about whether the response to the threat was strong enough and thorough enough. The debate was touched off by a front-page article last week in The Wall Street Journal charging that, for lack of effective action, "one of the most potent cancer-causing agents known to science is coursing into the nation's food supply." The article said the toxin was finding its way into breakfast cereals and other processed foods as well as into milk produced by cattle that were being fed contaminated grain.

### 'Several Layers of Protection'

But in a statement issued by its spokesman, William M. Grigg, the Food and Drug Administration said:

"There is plenty of aflatoxin-free corn available for human consumption, and several layers of protection are in place."

In October, the F.D.A. relaxed a standard that had permitted no more than 20 parts per billion of aflatoxin in corn moved in interstate commerce. While it did not relax the standard for corn processed for human consumption, the agency decided, to permit higher levels in livestock feed, up to 300 parts per billion for mature beef cattle.

The F.D.A. said this week that its tests of grain since Oct. 1 had shown about 6 percent, or 95 samples of corn of about 1,650, to be above the 20 parts per billion. The agency said those tests were concentrated in the most seriously affected regions, mainly in the Midwest. But it noted that while corn with that much aflatoxin cannot be used for human consumption, most of it is allowable for livestock.

It also said it had tested 263 samples of corn flour and corn meal and found about 2 percent, or six samples, to have more than 20 parts of aflatoxin per billion. "Incidentally," it added, "that aflatoxin would be significantly reduced by cooking."

> Aflatoxin, which flourishes in dry weather, can cause cancer.

It also said that in tests of about 100 finished corn products, including cooked and dry cereals, tortillas, corn chips and popcorn, all had proved negative.

### Varying Frequency of Sampling

The sampling conducted on the corn moving through the nation's food chain is conducted with widely varying frequency, by a variety of agents and at many levels. The main responsibility for inspections rests with the F.D.A., but at country grain elevators that agency may test only once or twice a year. In years of high susceptibility, those elevators are likely to test their own grain more frequently, and the large grain companies like Cargill and the Continental Company say they conduct continuous testing to make sure they are not buying tainted products or grain that will contaminate the inventories already held in their bins.

The Federal Grain Inspection Service, an Agriculture Department agency that u... ly checks and grades grain for quality, also tests for aflatoxin but usually only upon request by a buyer or other regulator.

### Mold Flourishes in Drought

Aflatoxin is produced by the fungus Aspergillus flavus, a mold that flourishes under conditions like those that prevailed in the Midwest last summer. In most years, Midwestern grain is generally free of aflatoxin and relatively few tests for the substance are run. The last year of widespread infestation and intensive testing was 1983, another drought year. Infestations are more frequent in the Southeast, which is also a less prominent grain producer.

A preliminary test is normally run on samples from loaded trucks with a "black light," under which a luminescent glow will expose the presence of suspect kernels. If the "glowers" appear, a further test, with chemicals, can be run at the elevator, but when suspect grain appears, the F.D.A. will often require that it be held until a further test at a laboratory can be run.

When tainted grain is detected that does not necessarily mean that it will be wasted. It is possible for a handler legally, under Government supervision, to blend it with cleaner grain to meet quality standards.

Although Government agencies, spokesmen for grain processors and trade organizations like the National Grain and Feed Association defend the testing process, hardly anyone is arguing that the surveillance system for grain could not be further improved.

### Review of Testing Suggested

Agriculture Secretary Clayton K. Yeutter suggested this week that a review might be in order, though others noted that the primary responsibility rests with the F.D.A.

John R. Wessel, the director of the F.D.A.'s contaminants policy staff, said, "I would have to agree that Federal controls and certain state controls could be improved."

Officials and other experts in Iowa and Illinois said that the higher levels of aflatoxin were found in tests run at the beginning of the harvest when the most susceptible and that later sampling showed lower levels of contamination.

"I don't want to leave the impression that we are not concerned, but I don't think anyone is well served by overstating the problem," said Roger Ginder, an agricultural economist at Iowa State University who was a member of a team that conducted his state's early test run.

### Higher Levels in Early Samples

Of 96 samples taken in 48 Iowa counties in the first week of September, Mr Ginder said, 29, or about 30 percent, showed aflatoxin levels above 20 parts per billion.

Daryl Frey, who heads the Iowa Agriculture Department's laboratory division, said 20 percent of 82 tests his unit had run for the F.D.A. more recently had shown aflatoxin levels above 20 parts per billion.

In Illinois, Jim Onken, superintendent of the division of grain industries and consumer services, said early test runs last fall had shown contamination levels above 20 parts per billion in 35 percent of the samples but that they were now running at about 20 percent.

In a similar vein, Ronald Phillips, a spokesman for the United States Feed Grains Council, an organization of exporters, said that most foreign buyers required aflatoxin tests and guarantees against contamination and that no shipments abroad had been turned away.

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FOCUS

National Grain and Feed Association

Volume 7, Number 7, March 2, 1989

# Op/Ed Article for The Wall Street Journal

The Wall Street Journal's Feb. 23 article pertaining to aflatoxin contained factual inaccuracies and innuendos, and presented a grossly unbalanced portrayal to its readers. The fact is the grain, feed and food industries take aflatoxin seriously and have developed and implemented reliable programs for detecting and keeping it out of the food supply.

The undersigned organizations representing major sectors of America's food chain would like to offer a fuller, more realistic and more balanced record to provide your readers with a better basis to judge the situation for themselves.

First, the presence of aflatoxin in corn is much less prevalent than implied, without attribution, throughout Scott Kilman's article. At one point, Mr. Kilman alleges that one-third of the official samples from the 1988 corn crop tested in Iowa and Illinois contain "dangerous levels of aflatoxin."

Fact: The data are skewed because abnormally high levels of aflatoxin were measured in premature, weather-stressed corn sampled early in the harvest before normal field drying occurred. Incidentally, such early testing is part of the industry's conscious effort to identify the quality of the new crop and assess potential aflatoxin risk, and to mobilize to deal with it.

Further, it is to be expected that the percentage of corn testing positive for aflatoxin is greater in official samples, since such samples in most cases were already suspected of containing aflatoxin in initial screening tests before being submitted for followup official laboratory tests. Mr. Kilman also fails to note that the majority of the Iowa and Illinois crop testing positive for aflatoxin was at levels less than 100 p.p.b., a level that scientific studies have found to be safe for feeding to all types of meat-producing livestock. Thus, even these data are not indicative of the overall quality of the corn crop in these, or other, corn producing states.

Data compiled by the Food and Drug Administration found that 93 percent of the harvested whole corn collected in random samples had less than the 20-parts-per-billion level deemed safe for human food. Only 2 percent of milled corn products prior to cooking had aflatoxin exceeding 20 p.p.b. Yet, even these data represent a "worst-case" situation that make them unrepresentative of the corn crop as a whole for two reasons: First, they were collected in areas most susceptible to aflatoxin. Second, FDA focused much of its sampling at targeted facilities or distribution points where the agency has found problems previously.

It also should be emphasized that emergence of aflatoxin in Midwestern corn was confined mostly to isolated areas of Iowa and Illinois, and was not prevalent in most of the major corn-growing areas of those two states. Little to no aflatoxin was detected in such major corn-producing states as Indiana, Minnesota, Nebraska and Ohio.

Second, the article may leave readers the impression aflatoxin is a perennial and pervasive problem.

Fact: That simply is not the case. The occurrence of aflatoxin, particularly in the major U.S. corn-producing states, is infrequent. Aflatoxin develops in years when extreme weather vagaries occur, such as periods of extreme drought-induced stress as occurred in 1988. In most crop years, weather conditions simply are not conducive to a general occurrence of aflatoxin.

Third, of particular concern to us is the impression Mr. Kilman's article seems to be trying to convey, again without attribution, that there is "widespread ignorance and disregard for the hazards" associated with aflatoxin.

Fact: This, too, is inaccurate. To the contrary, the industry moved quickly to respond to the potential incidence of aflatoxin in 1988 as soon as it was detected in early field samples. Each of the undersigned organizations published and distributed extensive factual information on aflatoxin, ways of detecting it, and the Food and Drug Administration's regulatory policy concerning seizure of interstate shipments of corn containing aflatoxin exceeding legal limits. Indeed, sales of various aflatoxin-testing devices to grain elevators and producers skyrocketed this year following initial reports that conditions might be conducive to the emergence of aflatoxin. Checks with just four manufacturers of such testing equipment found that more than 500,000 tests had been sold to elevators and producers to screen for the presence of aflatoxin -- hardly a barometer of "widespread ignorance."

Fourth, it's improper and irresponsible to allege, as the article does, that "regulatory efforts to stop the spread of tainted grain... have largely failed."

Fact: Curiously, much of Mr. Kilman's own article largely refutes this assertion. The article is replete with incidents in which corn with aflatoxin exceeding permissible levels was detected and unloaded, or milk with unsafe levels was dumped. Indeed, FDA and state inspectors were visibly present in areas which experienced aflatoxin this year, and reinforced the importance of sampling incoming shipments starting at the country elevator level. Widespread sampling also was conducted by university grain scientists, state and other federal agencies, and the industry itself. Each of these safety checks is performed at grain elevators, feed mills, processing plants and distribution points, long before products ever reach the consumer, foreign buyer or intended animal use.

Moreover, processors and food companies have in place extensive quality control programs, utilizing sophisticated laboratory tests to detect the presence of aflatoxin in incoming shipments before such corn is ever processed for human use. Likewise, processors and food companies have written surveillance plans and extensively test finished products to ensure safety. Further, the corn refining process itself, which transforms corn into such products as corn starch, corn oil, high fructose corn syrup and corn sweeteners, prevents mycotoxins such as aflatoxin from entering the food chain.

Fifth, it is inappropriate to suggest, as the article does, that since FGIS does not require mandatory aflatoxin testing for export shipments, such testing is not being performed.

Fact: Exporters routinely test incoming and outbound shipments for the presence of aflatoxin. The reasons are simple: First, virtually all export grain contracts specify that corn be aflatoxin-free. Second, grain containing unacceptable levels of aflatoxin are considered to be of unmerchantable quality, and can be rejected by foreign buyers at exorbitant cost to the exporter. In addition, foreign buyers can -- and most do -- require aflatoxin testing as a condition in the export contract itself. These tests are, in fact, done by FGIS utilizing the most sophisticated laboratory techniques available.

It bears emphasizing that in the highly competitive world grain export business, in which an abundance of potential suppliers exist, exporters can ill-afford to ship corn that is less than wholesome. No wonder FGIS states it has not received any confirmed reports of shipments of corn received at export destinations containing violative levels of aflatoxin.

Sixth, the article seems to suggest country and terminal elevators indiscriminately accept and sell contaminated corn into domestic and export channels.

Fact: This, too, is not the case. Local grain elevators that take delivery and commingle corn containing aflatoxin in storage risk having the contents of their entire elevator seized and condemned by state and federal officials if they subsequently ship corn containing aflatoxin at levels exceeding legal limits -- a prohibitive economic risk. And, as noted previously, subsequent commercial purchasers of corn containing aflatoxin above permitted levels can and do reject such shipments as being unmerchantable, at prohibitive expense to the shipping elevator.

In our view, a more representative description of industry practice goes like this. In the infrequent years when conditions for aflatoxin are present, local elevators and producers survey their local corn crop conditions prior to harvest, observe proper grain drying and harvesting techniques, and prepare to implement screening for aflatoxin before the first bushel is delivered. If aflatoxin is detected, the corn either is rejected or isolated in a separate bin to avoid contaminating the elevator's entire stocks. Samples of suspect corn then are sent for laboratory chemical analysis to confirm whether aflatoxin is present, and at what levels. Once the laboratory results are received, the corn either is rejected or diverted into feed if it contains levels safe to the feeding animal, or sent to industrial uses.

Further, U.S. grain facilities have implemented corn storage and handling practices involving drying and proper aeration to minimize, if not eliminate, the possibility of aflatoxin developing once the corn is stored.

Finally, the article alleges producers and elevators are encouraged to divert corn containing aflatoxin into illegal uses.

Fact: Congress recognized the financial harm a producer could experience because of aflatoxin when it passed the drought disaster-assistance legislation last year. Producers are eligible for disaster payment on corn containing aflatoxin at levels above those permitted by FDA. Further, producers are obligated to deliver aflatoxin-free corn as collateral for government farm programs. Warehouses storing government-owned corn are similarly obligated.

While these factual inaccuracies and misimpressions are troubling enough, even more disturbing is the erroneous impression that the nation's food and feed industry and government regulators have looked the other way. To the contrary, they have moved expeditiously to address the problem head-on, and to protect U.S. consumers and export customers alike.

All told, **The Wall Street Journal** has provided a distorted and misrepresentative portrayal of the entire U.S. food and feed chain. Your readers -- and American agriculture -- deserve better.

Sincerely,

National Corn Growers Association
National Council of Farmer Cooperatives
National Grain and Feed Association

LIFESTYLE

*HEALTH*

# A Scare in the Corn Belt

## Does a carcinogen threaten America's No. 1 crop?

The headline for last week's Wall Street Journal article on tainted corn didn't pull any punches: SPREADING POISON, read the first line, followed by FUNGUS IN CORN CROP, A POTENT CARCINOGEN, INVADES FOOD SUPPLIES. The story described how the U.S. corn crop had been contaminated with a deadly toxin because of last summer's drought and estimated that "tens of millions of bushels" have been contaminated, threatening foods made from the grain, as well as meat and dairy products from animals who eat it. Though the carcinogen, aflatoxin, hasn't been proven to cause the disease among humans, it does cause liver cancer among laboratory rats, and the Journal quoted a food-safety advocate as saying, "Ten to 20 years from now, there will be more [human] cancers because of this."

While acknowledging contamination, agriculturalists quickly disputed the Journal's conclusions. Malcolm Shurtleff, a plant pathologist at the University of Illinois, charged that the Journal was "making a mountain out of a molehill." The federal government has clear standards regarding how much aflatoxin can be in corn shipped between states. Said Daryl Frey of the Iowa Agriculture Department: "The public should be confident that their food supply is safe." And bad as the 1988 tainting was, aflatoxin contamination happens each year, normally on a much lower level. "We saw the problem coming," said Ralph David McQueen, a University of Illinois veterinarian. "It's being managed very well."

These reassurances might have inspired more confidence if the Journal hadn't revealed gaping holes in agriculture's regulatory net. The Journal told how corn sampled at one elevator was shipped weeks before FDA test results (disputed by the company) revealed it had five times the allowable level of aflatoxin. Equally troubling was the easing of some FDA aflatoxin standards just to increase the amount of corn that could be legally sold. This also happened after the droughts of 1980 and 1983. Higher levels are now allowed for corn fed to certain beef cattle, hogs and poultry. Not relaxed, however, were limits on corn intended for human foods, such as cereals, or for dairy animals or for milk.

It's impossible to say how severely aflatoxin will affect public health. Not all corn, for instance, is affected. Sweet corn—canned, frozen and on the cob—tends not to be damaged by the fungus that produces the toxin, and so does popcorn. Other major grains aren't susceptible, either. Some corn unacceptable for humans goes to livestock which eventually get eaten by people, but experts say aflatoxin levels in meat are barely measurable. Ironically, the same drought that encouraged the growth of aflatoxin has blunted its impact: only 4.9 billion bushels of corn were harvested last year, compared with 7 billion the year before. Agriculture officials also report that much of the corn now being used is from the largely uncontaminated 1987 harvest. Big users of corn, such as Kellogg and Pillsbury, check their supplies carefully. Even if the aflatoxin survives after it is processed into meal, flour or grits, it can be significantly reduced by cooking.

At the very least, the Journal story may help to clarify the extent and consequences of the contamination. On the day it appeared a Kansas congressman called for a House agriculture subcommittee hearing on aflatoxin in March. "I don't want to get people panicked," said Rep. Dan Glickman, "but I don't want to ignore it if it's as serious a problem as some people think it is." For Americans, who eat an average of 160 pounds of corn and corn products per year, the answers can't come soon enough.

RON GIVENS with KAREN SPRINGEN in Chicago and TIMOTHY NOAH in Washington

JIM PICKERELL—BLACK STAR

**Growing concern:** *Picking good corn (1985)*

## Pouring It On for Good Health

Which of the following is true?

A. *The earth is flat.*

B. *Elvis is alive.*

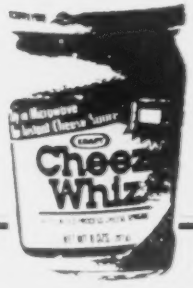
C. *Cheez Whiz is good for you.*

The answer is "C." Cheez Whiz may help in preventing cancer. That's the conclusion of researchers at the University of Wisconsin, who have been looking into a group of fatty acids that seem to have the effect of inhibiting some types of cancer in mice.

Known collectively as CLA, these altered fatty acids can become incorporated into the cells of those who eat them, establishing a permanent defense against cancer. Previous research by the Wisconsin group detected the presence of CLA in raw ground beef, and—in significantly higher concentrations—in grilled beef. Now in the January/February issue of the Journal of Agricultural and Food Chemistry, the researchers report finding CLA in milk and cheese as well. The champ of cheeses: Cheez Whiz, with 4.5 times more CLA than Parmesan, the next most CLA-rich cheese tested. Cheez Whiz's high concentration of whey, which is rich in the proteins lactalbumin and lactoglobulin, seems to help in fostering the reaction that produces CLA from linoleic acid.

The implications of this research are stunning: Cheeseburgers may actually be considered health food. If only Elvis really were alive. Just think how happy he would be.

**A cancer fighter?** *Maybe*



# REVIEW OF AFLATOXIN IN U.S. CORN

MONDAY, APRIL 2, 1990

HOUSE OF REPRESENTATIVES,
COMMITTEE ON AGRICULTURE,
SUBCOMMITTEE ON WHEAT, SOYBEANS, AND FEED GRAINS,
*Washington, DC.*

The subcommittee met, pursuant to call, at 3:10 p.m., in room 1302, Longworth House Office Building, Hon. Dan Glickman (chairman of the subcommittee) presiding.

Present: Representatives English, Penny, Jontz, and Roberts.

Staff present: Glenda L. Temple, clerk; Greg Frazier, Anne C. Keys, James A. Davis, and Cliff Humphrey.

## OPENING STATEMENT OF HON. DAN GLICKMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF KANSAS

Mr. GLICKMAN. Good afternoon. The subcommittee will come to order.

Thank you for joining this hearing today.

Almost 1 year ago, the subcommittee held a hearing in response to reports of high levels of aflatoxin in the 1988 corn crop.

At the hearing, the subcommittee received testimony from the Federal Grain Inspection Service of the U.S. Department of Agriculture, scientists involved in aflatoxin research, and representatives of the U.S. grain marketing system.

At the conclusion of the hearing, it was clear to me that more study was needed to determine if the current aflatoxin testing system now in place in the United States is adequate to screen out contaminated corn in years of widespread as well as regional drought.

Accordingly, Mr. Jontz of Indiana and I requested the GAO to conduct a study on this issue to be completed in time for the 1990 farm bill.

Although the report will not be released until this summer, I am glad to welcome GAO here today to discuss its preliminary findings on aflatoxin.

GAO auditors have traveled around the Midwest to investigate the adequacy, frequency, and preventive measures grain elevators and food processors use to monitor aflatoxin in corn.

Also, they traveled to Georgia to inspect the operational aspects of mandatory aflatoxin testing of peanuts to get an idea about how a similar system, although much larger, would operate for mandatory testing of corn.

I look forward to hearing their comments on its findings and appreciate Mr. Harman's attendance.

Also, I would like to welcome Dr. Phillips from the Council for Agricultural Science and Technology.

This group has recently released a study on mycotoxins.

While Dr. Phillips will discuss these findings on aflatoxin, he will also touch on some other mycotoxins which exist in our food chain.

Before I recognize Mr. Evans, our colleague from Illinois who is here, I would like to make special reference to—I understand there are several folks from Kansas--the Kansas Farm Bureau, leaders of the year awards.

Why don't you all stand up so we can see who is back there in that group. [Applause.]

Mr. GLICKMAN. We welcome all of you to today's hearing.

Mr. Jontz.

## OPENING STATEMENT OF HON. JIM JONTZ, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF INDIANA

Mr. JONTZ. Yes, Mr. Chairman.

First, let me thank you very much for your assistance in addressing this issue of aflatoxin and most particularly for scheduling today's hearing.

As you know, I have been interested in this subject since the hearing that this subcommittee held just about 1 year ago.

Obviously as a representative of the district where a great deal of corn is produced, I am concerned about the economic well-being of the agricultural sector of our economy.

But at the same time, I believe that more can and should be done to improve the safety of America's food supply. And with the issue of aflatoxin, I believe that we are in a position perhaps where some preventive measures might be appropriate and might be the best thing for both the consumer and the producer from a long-term perspective.

As you know, I have introduced H.R. 2641, the Aflatoxin Food Safety Act, to prevent problems from occurring due to the contamination of corn by aflatoxin.

After consulting with farm organizations, the grain industry, and consumer groups, this bill was filed and has been reviewed and I hope will be enacted in some limited form as a part of the 1990 farm bill.

The legislation represents something of a consensus among both farm and consumer interests about responsible steps which can be taken to address the aflatoxin problem.

First of all, the bill would require USDA to establish standards for aflatoxin testing procedures, and most importantly for sampling techniques.

The growth of testing has brought with it a great deal of variation among tests, and at the same time varying levels of accuracy.

From the standpoint of both the consumer and the producer, efforts by USDA to standardize and improve the accuracy and validity of tests for aflatoxin is necessary and desirable.

The second thing the bill would do, and this is probably the least likely provision to find its way into the 1990 farm bill, is to require the USDA to make indemnity payments to producers of corn who

because of damaging weather or related conditions suffer financial loss because of aflatoxin contamination.

This provision was added because, in my opinion, indemnification is necessary to provide the incentive for the farmer with an aflatoxin problem to remove the grain from the food chain at the first point of detection.

For grain above 300 parts per billion of aflatoxin, indemnification would be at full market value because destruction of corn at or above this level is required.

For grain with aflatoxin levels between 20 and 300 parts per billion, USDA would be allowed to set indemnification levels appropriately based on the loss of value of the corn.

By being fair to the producer, we protect the interests of the consumer, too—by assuring that the incentive exists for the farmer to keep dangerous corn away from where it shouldn't be.

Third, my bill would require mandatory testing of all corn exports and imports for aflatoxin contamination, to protect our export markets. These provisions were added because during testimony before this subcommittee last spring, Kirk Miller, the Administrator of FGIS, testified that approximately 75 percent of all corn exports were already being tested, and there seemed to be no reason to not go the extra mile and test a hundred percent of exports.

I am very pleased that the Secretary of Agriculture has proposed to the Congress in his recommendation of the 1990 farm bill that the testing be extended to 100 percent of exports.

It seems to me that from the standpoint of protecting our foreign markets, making sure that the consumer gets the best possible value that we need to provide the assurance that only testing of 100 percent of exports can provide.

Finally, this bill would require the USDA to conduct research to determine safe levels of aflatoxin, and how best to handle, store, detoxify, and dispose of aflatoxin-contaminated corn. Research is the long-term answer to keeping aflatoxin out of the food chain. Should drought or other stressful weather conditions that cause the growth of aflatoxin occur in the future or other stressful condition, we ought to know as much as we can about aflatoxin, and be well prepared to control and prevent it.

There have been some developments over the past few months since introduction of my legislation.

We did have some local problems with aflatoxin this last year, and very much appreciate the interest of the Congressman Lane Evans and also the interest of Chairman de la Garza in part resulting from problems in his part of Texas.

Also, since the introduction of H.R. 2641, the Federal Grain Inspection Service has established standards for aflatoxin testing equipment, which meets levels of performance that they find acceptable and that certainly is also a step forward.

At the present time, in my view, the public does not have reason to fear that aflatoxin-contaminated corn will end up in the grocery story, but there are steps that we can and should take to provide additional assurances to the consumer and to prevent any loss of confidence in the safety of our Nation's corn.

That is what brings us here today.

In conclusion, Mr. Chairman, let me thank in advance the witnesses who will be speaking to us. I know their testimony will be helpful as we address this issue in the 1990 farm bill.

Again, my thanks to you, Mr. Chairman.

[The statement of Mr. Jontz follows:]

STATEMENT OF HON. JIM JONTZ, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF INDIANA

Mr. Chairman, first let me thank you for your assistance in resolving the problem of aflatoxin in corn.

As you know, I have been very interested for a long time in this issue. As a member of this committee I am of course concerned about the economic well-being of the agricultural sector of our economy. Profit is a word the farmer hasn't heard enough in recent years. Adding unreasonable expense to the cost of producing food hurts the farmer and makes it more difficult for him to earn a decent living.

But at the same time, I believe that more can and should be done to improve the safety of America's food supply. I want to improve the job our government agencies are doing and strengthen the laws which govern food safety where they need to be strengthened.

It is with this perspective that I became involved in the aflatoxin issue in March of 1989. After consulting with farm organizations, the grain industry, and consumer groups I introduced H.R. 2641, the Aflatoxin Food Safety Act, to prevent problems from occurring due to the contamination of corn by aflatoxin.

This bill has been endorsed by the National Corn Growers Association, Americans for Safe Food, and the National Farmers Union. It represents a consensus among farm and consumer interests about responsible steps which can be taken to address the aflatoxin problem.

H.R. 2641 would address four specific areas:

1. Require the USDA to establish standards for aflatoxin testing procedures and sampling techniques. The growth of testing has brought with it a great deal of variation among tests and varying levels of accuracy. From the standpoint of both the consumer and the producer, efforts by USDA to standardize and improve the accuracy and validity of tests for aflatoxin is necessary and desirable.

2. Require the USDA to make indemnity payments to producers of corn who because of damaging weather or related conditions suffer financial loss because of aflatoxin contamination. This provision was added because indemnification is necessary to provide the incentive for the farmer with an aflatoxin problem to remove the grain from the food chain at the first point of detection. For grain above 300 parts per billion (ppb) of aflatoxin, indemnification would be at full market value because destruction of corn at or above this level is required. For grain with aflatoxin levels between 20 and 300 ppb, USDA would be allowed to set indemnification levels appropriately based on the loss of value of the corn. By being fair to the producer, we protect the interests of the consumer too—by assuring that the incentive exists for the farmer to keep dangerous corn away from where it shouldn't be.

Third, my bill would require mandatory testing of all corn exports and imports for aflatoxin contamination, to protect our export markets. These provisions were added because during testimony before this subcommittee last spring Kirk Miller, the administrator of FGIS testified that approximately 75% of all corn exports were already being tested partly because of a decision by FGIS to test all corn exported to our three biggest customers. Japan, the Soviet Union, and Mexico.

It doesn't make any sense to only test corn sold to our best customers' or to those who request testing. Every foreign consumer of American corn is a valued customer, and should have assurances that the product they're purchasing is safe. And as we've seen recently during the public concern over cyanide in grapes and alar on apples, it takes very little actual contamination to cause a sudden drop in demand for food products.

Each time the alarm is sounded about dangers to human health from what is in or on our food, the public's confidence in the safety of our food supply is shaken. If confidence in the quality and safety of American corn were to disappear, the economic effect could be devastating. We must assure foreign buyers that our products are safe, and remove any chance that our competitors will use aflatoxin to take away markets.

I am pleased that Secretary of Agriculture Clayton Yeutter recently proposed that Congress mandate the testing of all corn exports to help protect our international

markets for corn, and I want to thank the Secretary for his endorsement of that portion of H.R. 2641.

4. Finally, this bill would require the USDA to conduct research to determine safe levels of aflatoxin, and how to best handle, store, detoxify, and dispose of aflatoxin contaminated corn. Research is the long-term answer to keeping aflatoxin out of the food chain. Should drought or other stressful weather conditions that cause the growth of aflatoxin occur in the future or other stressed condition, we ought to know as much as we can about aflatoxin, and be well prepared to control and prevent it.

Since the introduction of H.R. 2641 last May, several developments have occurred; We have seen more aflatoxin contaminated corn in the midwest in Congressman Lane Evans district, and in South Texas which is in Chairman de la Garza's district.

Also since the introduction of H.R. 2641 the Federal Grain Inspection Service has established standards for aflatoxin testing equipment and Secretary of Agriculture Clayton Yeutter recently proposed Congress include a provision in the 1990 Farm Bill to require mandatory testing of all corn exports.

At the present time the public does not have reason to fear that aflatoxin contaminated corn will end up in products at the grocery store. But there are steps that we can and should take to provide additional assurances to the consumer and to prevent any loss of confidence in the safety of our nation's corn.

Mr. GLICKMAN. Thank you. It is a pleasure to have our colleague and former member of this committee here to testify today, Lane Evans.

We appreciate your testimony today and you may proceed.

## STATEMENT OF HON. LANE EVANS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Mr. EVANS. Thank you, Mr. Chairman.

I want to congratulate you for holding the hearings and keeping a continued interest in this problem.

I strongly support Jim Jontz's bill which he has just outlined because this is an issue of concern to consumers who want to be assured of the safety of the food they eat and farmers who want to supply the best possible product for those consumers.

Unfortunately, rather than assisting farmers in meeting the goal of a healthy product, Federal Government policy has done little more than frustrate and confuse farmers.

As you may know, portions of my district in west central Illinois have had the misfortune of experiencing 3 straight years of drought.

These conditions have resulted in a greater than normal amount of aflatoxin-contaminated corn.

To illustrate the frustration of farmers in my district in dealing with this problem, I would like to relate several of their experiences during last year's harvest.

One farmer described to me how his truckload of grain was rejected by the local elevator when their testing equipment measured it at 40 parts per billion of aflatoxin.

However, when he brought the same grain back to the elevator the next day, it tested at less than 20 parts per billion and the elevator accepted the grain. I understand this happened to a number of people.

In another case, a farmer whose crop consistently showed a higher than 20 parts per billion level of aflatoxin at the elevators sent a sample to a certified laboratory for testing, a requirement for crop insurance claims. When that sample came back reporting a level of less than 20 parts per billion, the farmer was told to

submit a sample that seemed likely to have a higher level of aflatoxin.

At this point in the harvest, laboratory testing was taking 3 weeks.

Farmers had little choice but to hold the contaminated corn while they awaited test results. I understand that aflatoxin grows rapidly in improperly dried corn so this situation could have only exacerbated any existing problem.

In addition, there was confusion on the proper disposal of corn that had above 300 parts per billion of aflatoxin. Should it be burned; should it be buried?

In response to the many requests from the farmers in my district, who were totally frustrated and disgusted with the situation they faced, I asked the U.S. Department of Agriculture to dispatch personnel to the area to perform certified laboratory testing. I received a response from Assistant Secretary for Marketing and Inspection Services, Jo Ann R. Smith, which said, "Let me assure you that the USDA agencies are aware of the problems and stand ready to assist your producers."

However, no additional personnel was ever sent to the region and farmers were left to deal with the situation as best they could.

Although we all hope another drought will not occur, we have no control over a lack of rain. We can, however, help farmers minimize economic and physical damage to their crop while protecting the Nation's food supply.

The farmers of America make every effort to produce the safest, highest quality product for consumers. It is the responsibility of the Federal Government to see that they have every assistance in achieving this goal.

Thank you, Mr. Chairman for the time today to testify.

[The prepared statement of Mr. Evans appears at the conclusion of the hearing.]

Mr. GLICKMAN. Thank you, Mr. Evans.

I appreciate your statement and we will hear from GAO next who will pretty much tell us what they think the most effective way to deal with this problem is.

We appreciate your testimony very much.

Any questions?

Mr. Jontz.

Mr. JONTZ. With your permission, I would like to ask Representative Evans a couple of questions.

Are you aware as to whether some of your producers did suffer financial loss due to the aflatoxin contamination?

Mr. EVANS. I understand some of them did, although this is a small number of the producers affected. Many of them received crop insurance, although they went through this long process of having grain tested and at time results took up to 3 weeks and in the case of some individuals they had to send two samples.

Mr. JONTZ. So what happened to the contaminated corn that exceeded USDA levels?

Mr. EVANS. I think it was destroyed, but a lot of farmers weren't sure how it was actually to be destroyed.

Some farmers weren't sure if they should burn it or bury it.

Mr. JONTZ. Was it pretty much standard practice in your district this last year that the corn would be tested at the point of first sale to the elevators?

Mr. EVANS. Yes, it was, with inconsistent results.

Mr. JONTZ. With inconsistent results.

I appreciate your statement. I certainly appreciate your support for our legislation and thank you for that testimony with regard in particular to the experience of the local producers.

We have been very fortunate in my area that we have not had a problem, but that doesn't mean we won't sometime in the future and I think the time to deal with it is before it becomes more widespread.

Mr. EVANS. I thank the gentleman for his leadership on the issue.

Mr. GLICKMAN. The next witness is John Harman, Director of Food and Agriculture Issues, Resources, Community, and Economic Development Division, GAO.

Thank you for your testimony as well as for GAO's report on this.

You may proceed.

STATEMENT OF JOHN W. HARMAN, DIRECTOR, FOOD AND AGRICULTURE ISSUES, RESOURCES, COMMUNITY, AND ECONOMIC DEVELOPMENT DIVISION, U.S. GENERAL ACCOUNTING OFFICE, ACCOMPANIED BY CYNTHIA S. RASMUSSEN, SENIOR EVALUATOR, AND ED ZADJURA, ASSISTANT DIRECTOR

Mr. HARMAN. Mr. Chairman, thank you.

We are pleased to be here today to discuss the preliminary results of ongoing work we are doing at your request on aflatoxin, which is a naturally occurring toxin produced by a common fungus on crops such as corn and peanuts.

You asked us to develop information on, one, the relative food safety risk of aflatoxin; two, methods for detecting and controlling it; and three, the extent of aflatoxin in the U.S. corn crop.

At this point, I would like to introduce my colleagues at the table this afternoon.

On my right is Ed Zadjura, who is responsible for our work in the food safety area; and Cynthia Rasmussen, who is the evaluator in charge of the work we will be discussing on aflatoxin.

I will summarize the prepared statement.

Our work to date shows that first, although the presence of aflatoxin in food products is undesirable, it is not considered as serious as other food safety risks.

Microbial contaminants such as salmonella, malnutrition, and environmental contaminants such as lead, are all considered more serious than aflatoxin while pesticide residues and additives are considered less serious.

Further, although FDA has found a small number of instances where aflatoxin exceeded action levels, it does not consider the food supply to be at risk.

Following the 1988 drought, FDA found 5.5 percent of sampled whole corn shipments and 2.2 percent of sampled milled corn products contained aflatoxin exceeding the limits.

These products required additional processing which would reduce aflatoxin levels further.

Second, testing for aflatoxin, particularly in corn, is difficult because of the large volume involved and problems obtaining representative samples at all of about 8,000 locations where corn is traded.

Sampling is difficult because aflatoxin is concentrated in individual kernels of corn, infected kernels may not be evenly distributed in a bulk lot, there are differences in the aflatoxin level of individual kernels and aflatoxin is measured in exceedingly small quantities.

Only about 16 percent of the annual corn crop, about 1.2 billion bushels, is consumed as food and most of that is processed at about 100 mills.

Sample variability is less of a problem after corn has been milled.

Further, testing all corn marketed including that used for commercial feed will not always ensure that aflatoxin will be eliminated from the food supply.

Despite these difficulties, aflatoxin detection and control occurs through the efforts of Federal, State, and private groups. In addition to sampling, FDA requires manufacturers to follow certain quality control procedures.

Other Federal agencies also participate including the Agricultural Marketing Service, which oversees the testing of peanuts for aflatoxin, and the Federal Grain Inspection Service, which performs testing on grain and grain products on a request basis.

State regulatory agencies also play a role, but these activities vary by State.

Milling trade association officials told us aflatoxin testing has been a standard practice in their industry for years.

Third, information on the incidence of aflatoxin in the corn crop is inadequate for determining whether aflatoxin is a widespread problem.

A recent proposal by the Iowa Aflatoxin Task Force, however, offers a proactive approach to gathering additional information on the occurrence of aflatoxin in the corn crop.

This proposal calls for, one, a preharvest weather monitoring and early warning system to predict high-, medium-, and low-risk areas of aflatoxin formation; and two, at-harvest sampling to confirm or deny advance warning data.

The task force believes that such information would allow timely action by regulators, farmers, and manufacturers to minimize the effects of an outbreak.

I would conclude by saying, Mr. Chairman, that aflatoxin is a serious food safety concern, but it is not as serious as several other food safety risks.

An infrastructure of Federal, State, and industry groups exist to test and control the incidence of aflatoxin in the overall food supply.

At this time, FDA considers that supply to be safe from aflatoxin.

Nevertheless, the adequacy of testing procedures and whether additional testing is needed continues to be controversial, particu-

larly for the corn crop, and proposals have been made to increase testing.

If it is decided more testing is necessary, a logical point for additional testing is the approximately 100 mills where corn is processed into food.

This is at the point of greatest risk. The Iowa Aflatoxin Task Force's proposal also offers one approach for making this testing and control process more proactive and thereby possibly improving monitoring of aflatoxin.

That concludes my summary, Mr. Chairman. We would be pleased to answer any questions you may have.

[The prepared statement of Mr. Harman appears at the conclusion of the hearing.]

Mr. GLICKMAN. Thank you very much for your testimony.

Why don't we go to Dr. Phillips and then we can ask questions.

## STATEMENT OF TIMOTHY D. PHILLIPS, MEMBER, TASK FORCE ON MYCOTOXINS, COUNCIL FOR AGRICULTURAL SCIENCE AND TECHNOLOGY

Mr. PHILLIPS. Thank you, Mr. Chairman.

Today what I would like to do is give a brief synopsis of the report entitled "Mycotoxins: Economic and Health Risks."

Toxic fungal metabolites, known as mycotoxins, are chemically diverse, occur in a wide variety of substrates, including food and feed, and can cause both economic and health losses in humans and animals through disease and reduced efficiency of production. Mycotoxins can produce injury to animals, in addition to being food-borne hazards to humans. The economic impact of reduced productivity, immune suppression, subtle but chronic damage to vital organs and tissues, and interferences with reproductive capacity is estimated to be many times greater than that of livestock death.

The aflatoxins can cause liver damage, decreased milk and egg production, and suppression of immunity in animals consuming low dietary concentrations that do not cause overt disease. While the young of a species are usually most susceptible, all ages are affected, and typical clinical signs are gastrointestinal dysfunction, reduced reproductivity, decreased feed utilization, anemia, and jaundice.

A variety of other effects have been attributed to mycotoxins. Embryonic death, inhibition of fetal development, and abortions have been associated with ergot, aflatoxins, rubratoxin, and zearalenone in the rations of pregnant animals. Teratogenicity has been documented for aflatoxins, ochratoxin, rubratoxin, T-2 mycotoxin, zearalenone, and sterigmatocystin.

At least three mycotoxins—aflatoxins, ochratoxins and sterigmatocystin—are known to induce tumors in one or more species of animal.

The range and potency of mycotoxins in causing damage in animals make this group of naturally occurring toxins an ongoing animal health hazard and a constant risk for contamination of the food supply.

Humans are exposed to mycotoxins by consuming foods that were contaminated by fungi. Such exposure is unavoidable because there are finite limits to the extent that fungal growth can be prevented in foods.

Consumption of foods heavily contaminated with mycotoxins has resulted in acute toxicity episodes in human populations.

Such occurrences in the United States are unlikely because heavily contaminated and uncontrolled food does not normally exist. However, concern still remains for possible adverse effects resulting from long-term exposure to low levels of mycotoxins in the food supply.

The major concern has focused on the possible contribution of aflatoxin exposure to the development of Liver Cell Cancer—LCC. The assessment of possible adverse effects resulting from long-term low level exposure to aflatoxins is a difficult task due to methodological problems and uncertainties inherent in the currently available data and evaluation procedures.

A "weight of evidence" approach to safety evaluation suggests that in the United States, aflatoxins may not be as important a risk factor for human LCC as might be inferred by epidemiological studies conducted in Africa and Asia.

Techniques are under development to strengthen future human population studies by increasing the confidence in estimates of aflatoxin exposure.

Our current system of mycotoxin monitoring and control must be maintained to assure that exposure to mycotoxins in the United States remains low.

Many foods and feeds can be contaminated with mycotoxins before harvest, during the time between harvesting and drying, and in storage.

Aflatoxins have been detected in milk, cheese, corn, peanuts, cottonseed, brazil nuts, copra, almonds, pecans, figs, spices, and a variety of other foods and feeds. Corn, peanuts, and cottonseed are the most frequently analyzed domestic crops, while copra, pistachio nuts, brazil nuts, figs, and spices are of concern in imported products.

Many other mycotoxins, produced by various *Aspergillus, Penicillium, Fusarium,* and *Alternaria* species can contaminate food and feed, but the incidence and relative importance to animal and human health of these different mycotoxins has not been established.

Because mycotoxin contamination of foods occurs in a random manner, a mycotoxin-free food supply cannot be guaranteed. The ability to identify and remove all naturally occurring mycotoxins from foods and feeds is limited. Thus, it is important to establish realistic goals for mycotoxin management.

It is established that one-quarter of the world's food crops are affected by mycotoxins annually. Mycotoxins and their control impose discernible economic costs on U.S. crop, livestock, and poultry producers, grain handlers, and food and feed processors. The economic impacts of mycotoxins are derived directly from crop and livestock losses, as well as from regulatory programs designed to reduce risks of exposure to animals and humans. Yet, despite the

recognized economic impact of mycotoxins, we are unable to quantify losses adequately.

The incidence of mycotoxins in the United States varies among commodities, years, and regions. Years of extreme drought and other environmental conditions favorable to aflatoxin development are more likely to result in higher economic losses, although even then, losses may occur randomly, making prediction and aggregate cost estimates difficult.

Economic losses are inextricably linked to regulatory standards. Food and Drug Administration guidelines are conservative to assure that risks are minimal, but flexibility exists to balance health risks with an adequate food and feed supply. To this end, exemptions to guidelines have been made on a case-by-case basis when market disruption is threatened by widespread aflatoxin incidence.

International regulatory standards have critical economic implications. More stringent standards result in higher costs for producers and exporters, and can discriminate against developing countries. Overly restrictive and inconsistent standards can introduce significant barriers to trade. Because regulatory restrictions significantly impact losses, expected benefits of these restrictions must be accurately addressed. Standards must be based on sound health-based scientific data. To this end, improved economic information on incidence and associated losses are essential. Additionally, the increase in internationally traded agricultural commodities necessitates consistent, cost-effective control of mycotoxins.

In the United States, the aflatoxins are the only mycotoxins that are formally and specifically regulated. Aflatoxins are considered unavoidable contaminants of food and feed where good manufacturing practices have been followed and, as such, are regulated under the Food, Drug, and Cosmetic Act, section 402.

The FDA established more specific guidelines for acceptable levels of aflatoxins in human food and animal feed—that is, action levels—that allow for the removal of violative lots from interstate commerce. The action levels for human food are 20 parts per billion total aflatoxins, with the exception of milk, that has an action level of 0.5 parts per billion for aflatoxin $M_1$, a metabolite of aflatoxin $B_1$.

The development of rapid and field-practical screening tests for mycotoxins—that is, black light, minicolumns, and immunoassays—has greatly facilitated prevention through cost-effective monitoring programs that allow for the detection and diversion of contaminated crops and animal feeds.

Although rigorous guidelines have been long established for the preventive management of aflatoxins in crops—that is, recommended practices for growing/production, harvesting, handling, storage, processing/manufacturing, sampling and analysis—significant contamination can still occur. It is important to understand that good crop management techniques and practical methods of aflatoxin detection—although significant tools—do not provide a complete solution, because aflatoxin contamination is unavoidable, and sampling problems may easily bias aflatoxin analyses. Consequently, the development and utilization of safe and effective procedures for the decontamination/detoxification of aflatoxin-containing food and

feed would provide important additional protection from exposure to these hazardous substances.

Numerous strategies for the detoxification of aflatoxins have been proposed. These generally include methods of physical separation, thermal inactivation, irradiation, microbial degradation, and treatment with a variety of chemicals. The detoxification strategy that has received the most attention is the treatment of aflatoxin-contaminated feed with ammonia, that is ammoniation. Although ammoniation was apparently safe and effective in earlier studies, it has not been sanctioned yet by the FDA, due to incomplete information on the potential toxicity and carcinogenicity of reaction products. A new approach to the detoxification of aflatoxins is the use of inorganic adsorptive compounds, such as hydrated sodium calcium aluminosilicate—HSCAS or Nova™Sil—in the diet. These compounds possess the ability to tightly bind and neutralize aflatoxins in the gastrointestinal tract of animals. Recent studies indicate that HSCAS can reduce the adverse effects of aflatoxins in chickens and swine and decrease the level of aflatoxin $M_1$ residues in the milk of lactating dairy cattle.

A cooperative effort on the part of academia, Government, and industry to identify and implement viable strategies to solve the mycotoxin problem is clearly warranted. The effective utilization of safe and field-practical technologies for the detection and detoxification of mycotoxins—along with optimal methods of food and feed production, harvesting, handling, storage, and processing/manufacturing—will provide an integrated approach to the preventive management of mycotoxins.

Future needs in mycotoxins research include:

One, surveillance of commodities, foods, and feeds for the presence and quantity of mycotoxins.

Two, surveillance of human populations to assess the exposure level to selected mycotoxins.

Three, assessment of new methods to detoxify mycotoxins.

Four, development of consistent regulatory controls of mycotoxins for international trade.

Five, development of resistant plants to fungal and mycotoxin occurrence.

Six, development of biocompetitive agents for toxigenic fungi.

Seven, improvement of sampling and analysis of mycotoxins.

Eight, research on the effect of mycotoxins on animal and human disease through immunosuppression and interaction with other disease agents.

Nine, toxicological evaluation of newly discovered mycotoxins.

Ten, examination of the possible therapeutic and biocontrol nature of mycotoxins.

Eleven, an integrated worldwide assessment of the economic aspects of mycotoxins.

That concludes my testimony, Mr. Chairman.

[The prepared statement of Mr. Phillips appears at the conclusion of the hearing.]

Mr. GLICKMAN. I want to try to get to some degree the seriousness of the problem and, as I understand it, I want to go back to where I started from, that Mr. Harman, your conclusion is that while aflatoxin is a problem in terms of problems for humans, it is

down the list of food safety problems? I don't know how you would rank it, but it is not at the highest part of the list?

Mr. HARMAN. That is correct, based on our discussions with FDA officials and other people knowledgeable in this area.

Mr. GLICKMAN. My next question is neither one of you argue whether we should have some sort of national mandatory testing of corn and if we do, we have to decide at what point we ought to do that.

Do you have any personal feelings on whether that is good public policy and if it is needed right now?

Mr. HARMAN. I would argue it is good public policy to have a national testing program to make sure the food supply is safe.

The question is at what point do you do that testing?

Mr. PHILLIPS. I agree and also point out that——

Mr. GLICKMAN. I said a national mandatory-type program, not a voluntary program.

You believe at least at some point that the Government ought to require corn be tested then?

Mr. HARMAN. I would say that based on the work we have done to this point, we don't see that there is that much need beyond what is currently being done because the information that we have at this point is that there is not a high percentage of the food that is entering the market that is contaminated with aflatoxin.

There are some—the problem we are dealing with here is beyond the simple fact of what percentage is entering the food stream. It gets into food safety issues, one of perception.

It doesn't take a lot before—the Alar situation, for example, was a good example of that—before you have ruined a market because you haven't done good testing.

We won't argue that there is not a need for additional testing.

We would argue that what we need is more information, better testing, and I hear that this afternoon from Congressman Evans. I heard it when Congressman Jontz opened up with his statement and his proposed legislation offering some additional encouragement for testing and for improving the research.

So there is more information that is needed before I think we would say that you need a national mandatory testing system that is envisioned by the piece of legislation that the Congressman has introduced at this point.

Mr. GLICKMAN. Dr. Phillips.

Mr. PHILLIPS. Apparently there is quite a bit of testing that is done for aflatoxin and this occurs at a lot of different levels.

Different commodities are tested by the FDA, by various State regulatory agencies, and now also by grain elevators.

One thing we shouldn't lose site of is that there is a real problem with the sampling bias.

No matter how good the assays—and we are seeing the development of immunosorbent assays that are much more cost effective—if there is a bias in the sampling it is going to give us false/positives and false/negatives.

Maybe before we set about to again enhance testing from the level it is already at, we should make available some funds to look at sampling and the types of testing we have available.

Maybe we should be looking into better ways to sample these lots so we have more of an accurate——

Mr. GLICKMAN. Mr. Jontz has a bill which, in many respects, dramatically augments the Government role in the aflatoxin area, both in terms of testing as well as in terms of indemnification.

Do you think that is in concept good or do you think it is premature?

The indemnification side is our decision to make, but in terms of the basic thrust of the bill, do you think that we are not there yet, the problem isn't that serious yet or it is something that we ought to do?

Mr. PHILLIPS. I certainly think—again this is my opinion—but from what we have seen in the extant scientific literature, these compounds pose serious health hazards to animals as well as humans and anyway that we could facilitate detection of these compounds and prevent some of the problems that we have seen—for instance in 1988 and in 1989 with aflatoxin—would be welcomed.

If we increase testing, if we increase the size of the sample, the size of the subsample, if we grind the particle even finer or increase the number of analyses, it has been shown that we reduce the error or the variance.

I want to point out though that there is still a sampling bias.

Mr. HARMAN. I think the problem that we run into with the proposed legislation has to do with testing at the point of first sale.

Mr. GLICKMAN. You really think that if you are going to test it, it ought to be at the mill?

Mr. HARMAN. We think that would be much easier. Problems are not as great at a mill. You are not talking about near as many sampling points.

One of the problems with sampling at the elevator is there are so many of them and it is going to take time to do the sampling and there is a feeling among several experts that that will maybe tax the elevators to the point where they can't handle it. It will back up, especially at harvest time.

That is another concern.

It just seems to us that the mill may present a better place to sample.

As you said, the indemnification question is another question.

Mr. GLICKMAN. If we did require mills to test, should we mandate standardization of testing equipment?

At the last hearing, we had a couple different ideas on what that test equipment ought to look like.

It looks to me like we need some sort of calibration between the testing apparatus.

Mr. PHILLIPS. I think testing should be consistent. There are a lot of different types of tests in the market now, especially the new immunosorbent assays which allow us to prescreen.

We certainly would need to look at the possibility of being consistent with the types of testing that are ongoing.

Mr. GLICKMAN. I just have one final question before I yield to the other members.

What percentage of corn is tested for export? Do we know right now?

Mr. HARMAN. Let me let Cindy answer that.

Ms. RASMUSSEN. The most recent statistic that we have heard is 90 percent.

Mr. GLICKMAN. Ninety percent of corn is tested at export and where is that corn tested? At a terminal elevator?

Ms. RASMUSSEN. At the export point.

Mr. GLICKMAN. Which would be where?

Ms. RASMUSSEN. In the Gulf of Mexico or the Great Lakes, the sampling would take place after the grain has been elevated a final time and drawn by mechanical diverter sampler——

Mr. GLICKMAN. Why don't we test 100 percent of corn for export?

Ms. RASMUSSEN. There is no mandatory testing for export. There would be testing if it was at the choice or request of the buyer or seller.

Mr. GLICKMAN. So most of that is done pursuant to contractual arrangements?

Ms. RASMUSSEN. Yes, sir.

Mr. GLICKMAN. How much do we test of the corn used in the domestic-market food chain?

Mr. HARMAN. I don't think we know that answer. It is not a very large percentage.

Let me add to that, too, testing for food, in other words, corn that goes into the food system from what we understand, what we were told by particularly the large processors is tested at almost 100-percent level and they have stricter standards in terms of the food that they purchase, the corn that they purchase. That is their own process.

Of course, FDA does have a certain oversight responsibility over that process and that is where their sampling enters into it.

So it is not to say a very small percentage of the corn, the raw product is tested, that is probably true——

Mr. GLICKMAN. So the U.S. Government participates in the testing of 90 percent of the corn for export, the U.S. Government doesn't participate that much in corn for domestic use, but that is done by companies themselves?

Mr. HARMAN. That is right.

Mr. GLICKMAN. Corn that would exceed, let's say, 300 parts per billion aflatoxin-contaminated corn that is fed to livestock, does that present danger at all to the food supply ultimately?

Mr. HARMAN. No.

Corn that exceeds 300 parts per billion cannot be fed to livestock. It has to be destroyed.

Mr. GLICKMAN. What if it were fed?

As a practical matter, if a person takes a load of corn to the elevator, it is 300 parts per billion and they won't buy it. That corn might be fed anyway.

What is the problem when run through an animal?

Mr. PHILLIPS. There could be animal health problems, as I stated earlier in my testimony, especially with regard to young animals.

Mr. GLICKMAN. For animal health—if that animal were then slaughtered, would that present problems for human health?

Mr. PHILLIPS. Generally speaking, the FDA sanction in 1988 allows feeding of corn up to 300 parts per billion at feed lots.

I expect that there is a bit of a safety factor built into the 300 parts per billion level and that basically you would have to get up to part per million levels before you would see more than trace levels in the meat, of feedlot, cattle.

Mr. GLICKMAN. Does the cooking process kill aflatoxin?

Mr. PHILLIPS. Aflatoxin is nonthermolabile.

Mr. GLICKMAN. What does that mean?

Mr. PHILLIPS. It is very heat stable.

If you have enough heat, you can get some degradation of aflatoxin. Research has shown that roasting temperatures can result in the breakdown of 40 to 60 percent of parent aflatoxin.

We don't know what all of the degradation products are, or whether or not they would still be toxic, but heat—to a certain extent—would break it down.

Mr. GLICKMAN. Thank you.

Mr. Roberts.

## REMARKS OF HON. PAT ROBERTS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF KANSAS

Mr. ROBERTS. Thank you, Mr. Chairman.

I want to echo your special welcome to the Kansas Farm Bureau leaders who are in the audience and I want to thank the members of the panel for their testimony.

I think we have a choice basically with regard to the aflatoxin problem or challenge—it is not a problem as much as it is a challenge.

We could go ahead with legislation and use that as a catalyst if you will, so that the USDA, FDA, and various State authorities and private industry as represented by the food processors work toward a more uniform means of testing, or we can continue with our oversight responsibility as we are doing with the able assistance of Mr. Jontz, Mr. Penny, myself, and other members of the subcommittee.

I am not sure at this juncture whether we need to do more especially with reference to the legislative initiative.

I have a little concern with regard to the indemnity program not in relation to being of help to the individual corn producer who found himself in a real fix and we certainly want to be of help to that individual, but as happens on this subcommittee, what is good for corn is good for wheat and what is good for wheat may not necessarily be good corn, and I can see a situation with an infinitesimal problem and sampling wheat, where do we draw the line.

It is a food safety problem that is one concern, and we also have an inspection problem.

Mr. Jontz has really focused the issue with regard to his legislation and that is why we are holding this hearing.

By the way, I want to thank you all for your continuing and ongoing help as we approach the food safety problem here in the subcommittee and in the Congress. You have been an invaluable partner in terms of research and hands-on suggestions.

You are really recommending with regard to mycotoxins and aflatoxin in regard to page 8 here on your future needs that we need research.

You have 11 different areas that it would be helpful to determine if, in fact, we do have a good safety problem as the chairman has asked; and second, we have, I think, something called an inspection problem.

By the way, the Department of Operations, Research, and Foreign Agriculture Subcommittee is now going over the research budget and it may be that we could focus some attention at least in this area to where we could be of help in regard to the laundry list that you have suggested.

We do have an inspection problem.

I want to warn my colleagues about the law of unintended effects.

I can remember the full committee and the Congress passed an updated Federal Grain Inspection Act, the clean grain issue, if you will—let the record show that no corn producer or no wheat producer in Kansas ever brought any unclean grain across the scales at any elevator, but there obviously were some in other areas.

After we passed this legislation and mandated certain standards, and I think it was good legislation we had to live with it and the service did the inspection right in the middle of the Kansas wheat harvest and several producers, more than several, were in touch with my office, and Congressman Glickman's office and others when their wheat, which they thought through the State Inspection Service had a classification of No. 1, No. 2, all of a sudden was sample grade and then that legislation was not nearly so popular as it was when passed, so in terms of a mandatory Federal Inspection System, I think we have to be careful where we are headed as to the practicality of it.

With regard to the GAO report and touching on the chairman's questions, if I might, on page 2 you have indicated, Mr. Harman, that when you are ranking food safety risks, that the experts in the field generally rank such contaminants as salmonella, listeria, lead, et cetera, as more of a risk than the aflatoxin.

That doesn't mean aflatoxin isn't a risk, but you are talking about something with a potential to kill humans after one exposure?

Mr. HARMAN. That is correct.

Mr. ROBERTS. What evidence do we have that we have suffered the loss of anybody with regard to aflatoxin?

Mr. HARMAN. We don't have any evidence.

Of course, our work was not designed to find that. There is no evidence that we could find that there is anybody in this country affected from a human standpoint by eating food that may have had aflatoxin.

Of course, what our work shows is a very low instance of aflatoxin in the food supply based on FDA's work.

Mr. ROBERTS. Of course, that is their bailiwick, but on page 3, you state that the FDA does not consider the food supply to be at risk.

Are you in agreement with that?

In terms of processed food on page 4, you indicate that back in 1989 primarily because of the drought and our concern over this, the FDA sampled 2,097 food products and found that 5.5 percent of

the whole corn shipments, and 2.2 percent of the milled corn products contained aflatoxin in excess of the 20 parts per billion limit.

I would tell my colleague and the chairman that with regard to the FIFRA statute if $x$ is determined to be a dangerous risk level then 10 to the minus $x$ is a safety level, so we have built in latitude.

Is that the same safety level that we are using here in terms of aflatoxin?

Mr. HARMAN. Yes, sir. I would say so.

Mr. ROBERTS. Then we are getting into the fact that only 16 percent of the corn crop is used for numan food and most of that is processed at 100 mills.

You are saying to the chairman and to us that if, in fact, we go to this kind of a system, the better place to do it would be at the mills?

Mr. HARMAN. That is correct.

Mr. ROBERTS. All right.

You go into considerable discussion over the Iowa Aflatoxin Task Force report and that report calls for a preharvest weather monitoring and early warning system to predict the high-, medium-, and the low-risk areas of possible formation and then a physical sampling at harvest time to confirm or deny this data.

Where are we with regard to the Iowa Task Force? Have they put that into effect in Iowa yet?

Mr. HARMAN. I don't think so.

Their report is out and it would take some additional work, particularly on the part of the Federal Government to implement that type of system.

Mr. ROBERTS. That was my next question because obviously we have—Iowa has the ground water law that is considered the model by some and obviously we have that to consider with the aflatoxin situation.

But you mention here, you are even recommending with regard to the dairy farmer that—no, I beg your pardon, that food processors would select locations from which to purchase their raw ingredients based on the information that we were able to sample test and you say that the National Agricultural Statistics Service would establish the risk areas and that would be the area obviously that we would be deficient.

I don't think these folks are ready to do that at this time.

Mr. HARMAN. That is correct, they are not.

I think this gets to what Dr. Phillips talked about. It is just the information you need to be able to make judgments about where do you test, more research on improving the tests, more research on the effects of this toxin—there is just more information that needs to be had before we feel at least that you can go to some sort of mandatory testing across the country.

Mr. ROBERTS. I am very much opposed to any mandatory testing program at this point. I don't see a need for it.

Mr. Jontz makes an excellent point in regard to that one individual who is the corn producer out there who has been found to have in excess of 300 parts per billion and what does he do? Does he burn it? Store it, ship it away, et cetera?

We apparently don't have the kind of networking that we need to have between the FDA and the USDA and the Federal Grain Inspection Service and the State folks as well as the food processor.

I would add, Mr. Chairman, that perhaps the food processors could be asked to come forth.

I know there is a theory around that you are asking the fox to guard the chicken coop with respect to food processors, but if they are involved in sales of products that are in excess of Federal standards, they are in a world of trouble and you pointed out they feel they are doing an adequate job.

I wonder how they would feel about a mandatory Federal program on top of what they are doing.

Mr. HARMAN. I don't think we asked them about that.

Most organizations in the private sector are not overjoyed about additional Federal involvement.

Mr. ROBERTS. I think that is an understatement.

Mr. Chairman, I think this has been a valuable hearing and I would hope that we could go forward with our oversight responsibilities and achieve a better network to respond to this when the situation occurs.

I yield back.

Mr. GLICKMAN. Mr. Jontz.

Mr. JONTZ. Thank you, Mr. Chairman.

I want to thank both Mr. Harman and Dr. Phillips for the excellent testimony.

Mr. Harman, let me ask you some questions first.

I have the impression from the testimony before this committee 1 year ago that action levels that FDA set are very arbitrary, and although perhaps it was not the subject of your audit, you would have some comments to offer in terms of where those are health-based risks, that some action levels set on health-based data were just how those action levels were set.

Other countries, as I understand it, in their purchase of corn, have standards that are considerably different than those levels.

Mr. HARMAN. That is correct, they do.

This is not by any stretch of the imagination an exact science, establishing these levels.

They are based on epidemiology studies. They are based on work and research that is done up to this point.

I don't think that anyone could say at this juncture that the 20 parts per billion is the appropriate level.

I think some of Europe has 5 parts per billion as a level.

Of course, I think sometimes when you get into what foreign countries are doing, you may have to look at it a little bit with some skepticism because you are not quite sure why those levels were set.

We didn't look at the European levels and we are not sure—we would have doubts about whether you can test accurately at that 5 parts per billion level.

Mr. JONTZ. Well, perhaps you can forward to the committee some summary of the epidemiological evidence.

My recollection is that 20 parts per billion was set originally because that is what was detectable and technology today is far better and I think that that is one of the key items for research, is

coming up with better evidence for the action levels, because I am not sure those epidemiological studies that you spoke of really are very conclusive.

Mr. HARMAN. I don't want to mislead you.

You are essentially correct they are based on what level you can sample.

Mr. JONTZ. Twenty years ago if we can sample.

Mr. HARMAN. I am not sure about that.

Mr. JONTZ. They were originally devised 20 years ago? Mr. Phillips, do you want to get in on this?

Mr. PHILLIPS. It is my understanding that that is correct. It was actually not the lower limit of detection back in the sixties when the aflatoxins were discovered. It was in the late sixties when the FDA imposed that, and it was based on levels that could be chemically confirmed, because when you look at aflatoxin, you can do a simple test, like the prescreens, but these don't hold up in court. So for regulatory action, one would need to followup with a confirmatory test such as G.C./mass spectrometry.

Mr. JONTZ. Well, let me ask this second question to you, Mr. Harman. Did you get the sense that the relative importance that the FDA officials you talked to about aflatoxin as a food safety risk compared to other potential risks was based on its acute toxicity or based on some understanding in FDA about the cumulative effect of low levels of exposure? Or both?

Mr. HARMAN. I will pass that on to Cynthia. See if she wants to say anything about that, but my understanding it is probably more the latter than the former, but go ahead.

Ms. RASMUSSEN. The relative ranking is something that dates back a number of years within the Food and Drug Administration, as well, with food scientists. It is a general ranking. It is my understanding that it would take into consideration the chronic affects of low-level dietary exposure.

Mr. ZADJURA. That is primarily what it is based on. The aflatoxin in large doses will clearly kill you. It is a potent toxin but 20 parts per billion for humans is based on long term, low-level exposure, set the same way for most carcinogens regulated by EPA, FDA, and anybody, as far as the epidemiological studies.

They are generally incomplete, inconclusive. There is no direct dose response relationship between what happens in animals and what happens in humans, and we set it at essentially a safe level. We set it, as I think Mr. Roberts said, 10 to the minus something.

Mr. HARMAN. But it is certainly an area, which as your bill addresses, that needs more research, more needs to be done on it. That is one part of the bill I think we would agree with.

Mr. JONTZ. Good. Now, let me proceed to another question, if I could. Those of us who are not familiar with FDA and the way that agency functions have trouble interpreting some of the numbers that you bring to us. The way I understand it, half a year, 9-month period most recently that you cited to us, FDA sampled about 2,100 food products and found 5 percent of the whole corn shipments and 2 percent of the milled corn products contained aflatoxin exceeding the limits.

If all of those 2,000 would have been whole corn shipments that would have been 100 samples, but they weren't all. We don't know

how much was based on this statement. Do you have some confidence that FDA is doing enough sampling? Is this consistent with the level of sampling they do of food products over all or how adequate is the resources that FDA has to do testing?

It seems to me 5 percent is a number of some significance. I guess it depends on whether that is representative of all food products or whether that sampling was done where there was some reason to believe there is a problem. I gather it is more probably the latter, so I have trouble really interpreting how much exposure that means to the American consumer.

Mr. ZADJURA. FDA does not do extensive monitoring of food products for aflatoxin. Essentially what they do is surveillance testing to see that the mills are following good manufacturing processes. The good manufacturing processes require the mills to either test or to buy the products from people who have certified to them under contract that they are below the FDA's limits of 20 parts per billion for aflatoxin.

Frequently, a lot of the mills, some of the mills we visited require in their contracts that it be 10 parts per billion or less. FDA, as I said, requires the mills to do this or do their own testing. The mills frequently test a product at intermediate and finished levels.

FDA then does surveillance testing primarily to see if they are detecting any problems that would indicate that manufacturers are not doing their own testing or certifying. They do limited testing. I think in an earlier year they only did 600 or 700 tests, but after aflatoxin was occurring, was supposed to be a problem, they increased their sampling. They increased their sampling in areas where—for example, Illinois—where they thought aflatoxin was occurring.

What they found was the levels were actually comparative to earlier years when aflatoxin wasn't considered to be a major problem and there wasn't a major outbreak in corn. What this tends to indicate is that FDA's sampling was biased toward areas that were known to have a problem.

The whole milled corn would—I mean the whole corn would require further milling and processing, even the sample that had 2.2 percent would probably require cooking or dilution of some means, and FDA concluded that—they believed the food supply was safe from aflatoxin.

FDA's testing is not done at a level or a volume that is significant and projectable to the entire universe. They looked where they thought there were problems and found still a relatively low level.

Mr. JONTZ. So you would say that 5 percent is a relatively low level?

Mr. ZADJURA. Given that you were looking at a crop from an area, and they even went to mills that they suspected may not have the best quality control programs—they were looking for the problems. It is like sampling all the bad apples essentially.

Mr. JONTZ. You mentioned in your response to that question that a number of food processors acquire the grain that they purchase to be certified to meet certain standards, and that that is the way that a lot of processors satisfy the FDA that they are——

Mr. ZADJURA. They usually buy it initially that way. They frequently sample further themselves. Some of the processors we talked to essentially have a system where at the end of the year they go back to the supplier, and if you have given them too many lots that are above, say, 10 parts per billion, if that is their standard, they reduce their contract with you.

It is economic self-interest. They are trying to protect themselves.

Mr. JONTZ. I understand that exactly. How much of that testing that is what they accept as meeting adequate standards is done at the country elevator?

Mr. ZADJURA. I would suspect that very little.

Mr. JONTZ. Where is the testing done?

Mr. ZADJURA. Probably at subterminals or processors farther along the line.

Ms. RASMUSSEN. One thing that we noticed is that grain, as it is traded before, say, it would leave a country elevator if it were going by unit train to a plant or to an export point that it would be sampled and analyzed by a private laboratory for aflatoxin.

It would not be a USDA test. It might be performed by the same organization that is performing the official grades on that particular unit train.

Mr. JONTZ. Sure. Those are the tests that showed so much variation.

Ms. RASMUSSEN. No, these would be comparable to official samples.

Mr. JONTZ. Well, did you look at that stage in the testing process? I mean, the anecdotal evidence that Congressman Evans presented to us today that I hear so many times is that the farmer shows up, he is told he has a problem, he goes to the next elevator. He is told he has a problem. He goes to the third elevator. They buy it.

Mr. ZADJURA. That is absolutely true.

Mr. JONTZ. I guess what this has led virtually everyone I have talked to, to conclude is that testing is not—the validity of testing is not as good as it should be, and part of that is because of sampling, as Mr. Phillips indicated to us, and part of it may be for other reasons. But I guess my question was are we accepting those test results as valid in terms of satisfying FDA that proper testing has been done?

Mr. ZADJURA. Mr. Jontz, there is several different levels of testing. For example, the first thing that could happen and that frequently happens at particularly small elevators is what they refer to as the black light testing.

You take a sample of the grain. The sample may just be a bucket that somebody sticks in the truck while it is being dumped, so it is not randomly selected. You stick it under the black light. If it fluoresces, it means it has aflatoxin or one of a number of other substances.

As a result, you have a 40 to 60 percent error rate. If your question is does this grain have aflatoxin because it is checked for other substances that also fluoresce, then you have to confirm it by other more sophisticated means. One of the tests that can measure whether it is 20 parts per billion or more takes over 1 hour to do.

Another one that can give you the specific level, whether it is 5, 15, 30, or 45 takes 4 hours to do. Whether these tests can be performed depends of course on whether there is no back up in grain deliveries—and it doesn't include the time for processing the grain, mashing it up, and so forth. All of those tests, if you haven't done a truly random sample, have problems. It doesn't matter how sophisticated the test is.

If you pick only the bucket of bad grain, it is going to show that the entire load is terrible. If you go to the next elevator or the next lab and give them a different bucket of grain, you get a different test result.

There are some quicker tests now that may only take 8 to 10 minutes and give better results. However, during peak harvest time, just about any of those would cause a major back up. We estimate, based on an average size load of 300 to 500 bushels and given that we market approximately 8 billion bushels of corn, that we would need between 16 million and 23 million tests, each one of those subject to sampling problems.

The tests can run—the test kit alone could run $10, so that is $160 million to $230 million and doesn't include labor, time, back up in the system.

Mr. JONTZ. I appreciate that. For better or worse, this testing is occurring.

Mr. ZADJURA. Yes. There is a little different testing that takes place at the mills because the grain has been essentially mixed together, mashed up, processed. You have a more uniform distribution of the aflatoxin if it is there, so you are getting a better sample, which is one of the reasons why the mills are a better place at which to test.

When you are doing individual kernels, there is no uniformity to it. At the mills where it is, like I said, being ground up and mixed together, you have a more uniform distribution. You are pretty sure if it says 20 parts per billion when you pull the next sample out it is going to be 20 parts per billion.

Is it difficult to get a good test done under proper laboratory conditions, at the warehouses, where you are getting truck loads dumped and they are taking 1 to 2 minutes to grade and sample? I talked to the statistician in our office before we came over here. He said yes, you could get a more representative sample if you dig down in this corner of the truck, one over here, one in the middle, one in the top. They don't take samples that big. They grab a 4-pound bucket. They grade it. They judge it for the various grading standards and cleanliness, and they look at it under the black light. It has either got aflatoxin or something they don't like or it doesn't.

As a result, you can very well drive your truck down the road and get another test, and it is OK there. Sample variability at that level is a real major problem.

Ms. RASMUSSEN. Similarly, the peanuts, the peanut industry experienced similar sampling problems at the onset of their program. When they started the sampling and the detection program, they were drawing a 10-pound sample for a lot of—about 200,000 pounds, and because of this variability, the way that they resolved it is instead of one 10-pound sample, which is kind of what we are

talking about in corn, they draw three 48-pound samples of peanuts, and then perform the analytical test result on the first sample that is ground.

If it falls outside a certain range, then they grind the second and the third.

Mr. JONTZ. So would you conclude that if we are going to continue to see a lot of testing at country elevators that there ought to be standardized—there ought to be standards for testing procedures and sampling techniques?

Are we being fair to the producer under the present system?

Mr. ZADJURA. I think that what occurred in 1988 and 1989, we have had producers that have had problems, like you say. They have had a lot rejected at one place or accepted at a different place. Particularly, in the early part of the harvest when we didn't have a good handle on this and before FDA was allowing blending to reduce the levels that you had producers who effectively had to dump loads of corn. Whether we have standardized testing— you could conceivably have standardized testing at the warehouses. However, it would cost a lot in terms of testing equipment. It would be difficult to enforce unless you had Federal oversight. You have the same problems if somebody wanted to essentially scam the system—they could, unless you had Federal inspectors there. It would cost a lot of money and take a lot of time.

It would give you a better handle on the grain at that point. It would not—it still would not assure that contaminated grain wouldn't get in the food supply. Also, during shipment and storage subsequent to that, the mold could continue to grow.

Mr. JONTZ. Well, I appreciate that answer, but I guess it doesn't—I am not really sure it addresses the question that I asked. Testing is now occurring at the country elevator level.

Mr. ZADJURA. That's correct.

Mr. JONTZ. People are being—are paying an economic price for that, the producer is. Now, it is occurring at this level for some reason, because the elevator wants to have some assurance that they are not buying a bad product, but if they don't test according to using sampling techniques and proportions that are fair to the producer, you have got one problem. And if they are not making valid tests, they are really not protecting themselves anyway.

So I guess my question is, are we being—are we—is this rather haphazard system that is now in effect at the country elevator where the validity is very low and where you impose certain burdens on the producer, is that a system we ought to be concerned enough about to at least require some uniformity of testing and sampling and all of that?

Mr. HARMAN. It is a difficult problem. There is no doubt about that. In theory, at least, I think we would agree that you should move toward some sort of way to standardize these tests, as long as you are going to use them.

Mr. JONTZ. Well, they are using them.

Mr. HARMAN. As long as you are going to do that, in theory, at least, you should try to move toward some sort of standardization so that research is playing the same song, but it is not an easy thing to move toward, largely because the technology is not there.

Mr. JONTZ. Mr. Phillips, you want to get in on this one?

Mr. PHILLIPS. Yes, I agree. I think we should try to move toward consistent sampling and testing at these places. Again, as you know, the problem is that these outbreaks are sporadic and what we have seen in countries other than the United States is that mycotoxins can cause problems in humans and, during droughts like we had in 1988 and 1989, we can have significant levels of these compounds, and we certainly want to have the mechanism there at our elevators to detect this problem before it goes any further.

Although a lot of corn is produced by the farmer, the dairyman, for instance, may produce his own corn and use it in his feed. I don't know how that is going to help him.

Mr. JONTZ. Well, I got the impression from your testimony that there may be a fair amount of damage to livestock from aflatoxin that we may not appreciate the extent of at the present time.

Mr. PHILLIPS. Yes.

Mr. JONTZ. That is something that we ought to be concerned about. I am not suggesting we can do on the farm testing, but I guess there is a certain cost there that we probably are incurring that we would have difficulty with.

Mr. PHILLIPS. It is sporadic. I am from Texas, and in August 1988, when we first noticed this problem, in Texas, we noticed it in milk. The dairies first noticed it after they had obtained corn from the farmers, and this is another example—like the feed mill—of a point where aflatoxin is homogeneous. So when you measure it, you have good accuracy, even though it is a very low level. The accuracy in milk is good because it is homogeneous, but it is really too late for the dairyman at that point.

Mr. JONTZ. I think the chairman wants me to try to wrap things up here. I have obviously taken a lot of time, and I appreciate your answers, but both Dr. Phillips and Mr. Harman, you certainly have made favorable comments with regard to the needs for research. And you have both made favorable comments with regard to at least moving toward uniform standards for testing procedures, sampling techniques, and testing equipment.

We really haven't discussed the export question, but I guess one of my concerns is what happens to contaminated grain at the export terminal, and I don't know whether you look at that or not. Do you want to try that one?

Mr. HARMAN. We didn't look at that in any sophisticated way that would identify problems or causes. I mean, there was all kind of anecdotal information indicating that there may be some blending going on at the terminals for corn.

It does exceed and then is being introduced and does not exceed.

Mr. JONTZ. Is that legal at that point?

Mr. HARMAN. That was legal at—I believe it was for the 1988 crop. It was legal.

Mr. ZADJURA. Provided that it wasn't going to be used for human consumption.

Mr. JONTZ. We know that when we send the grain overseas?

Mr. ZADJURA. It depends. The contract is essentially from the foreign buyer, and if the foreign government certifies that it is not, that it is going to be used for animal feed, then they can ask for anything they want. We heard a story that called for one contract

for corn where they only wanted to buy corn in excess of 300 parts per billion which in this country would have to be destroyed.

Of course, nobody could supply them with that corn. The best they could do was some corn with 100 parts per billion. The reason they may have asked for that was that they got it very cheap, and essentially they probably milled it down or used it for feed, but they were able to buy it cheaply that way.

Blending was allowed in 1988 and is the reason that a lot of the corn—there wasn't a lot of losses in the sense that if you had corn that had 100 parts per billion or above or even approaching 300, you were allowed to blend it under an approved plan to lower it down. And then you could only use it for the appropriate level of feed. You could not introduce it into the human food chain.

Mr. JONTZ. Thank you, Mr. Chairman.

Mr. GLICKMAN. Thank you. Let me just ask you a couple questions. The Peanut Program, there is an indemnification program in peanuts?

Ms. RASMUSSEN. That's correct.

Mr. GLICKMAN. What is the cost of that program?

Ms. RASMUSSEN. To the Government?

Mr. GLICKMAN. Yes.

Ms. RASMUSSEN. The indemnification takes place in two ways. One, if you are a handler, meaning if you are someone who purchases peanuts from farmers and mills them in preparation to sell them to a grocery manufacturer, if you have aflatoxin contaminated peanuts, you would be indemnified through a fund that you have contributed to.

Handlers pay an amount, an amount of dollars per ton to a fund, from which they would receive indemnification.

Mr. GLICKMAN. Is that a statutorily created fund or is that a voluntarily created fund?

Ms. RASMUSSEN. It is not the created bylaw. The Peanut Administrative Committee was established under the Agricultural Marketing Act. It is like a marketing agreement.

Mr. GLICKMAN. So they contribute, and the handlers contribute into a fund that they would then get indemnified back from?

Ms. RASMUSSEN. That's correct.

Mr. GLICKMAN. There is a second part to the indemnification?

Ms. RASMUSSEN. Producers would be indemnified under the Price Support Program. They in essence are guaranteed the quota price for peanuts for a certain amount of peanuts that they would produce, and if their peanuts were found to have aflatoxin, they would have less value, but under the Price Support Program with a small penalty, the producers effectively receive the full value.

Mr. GLICKMAN. Aflatoxin contaminated corn was part of previous Disaster Program payments, was it not, in 1989?

Mr. HARMAN. That's correct.

Mr. GLICKMAN. 1988 as well. Reduction in quality was viewed to be a quality disaster under the law for payments under the law?

Mr. HARMAN. That's correct.

Mr. GLICKMAN. I guess this whole thing leaves me a bit lost, I would say to you all and to Mr. Jontz as well, we know there is a problem there. I am not sure if we can—a system of indemnification at this stage concerns me because I am not sure that we have

a national testing procedure that makes any sense yet, so I don't know where to indemnify and to whom.

I could see no standards set up for indemnification. Maybe you could define one, but on the other hand, we have our dips and valleys in weather. We could find this problem continuing and increasing, and we have to give people the confidence that they are not buying this kind of contaminated grain, and you have to give farmers some degree of protection against it.

But if you provide a straight indemnification without any kind of controls on it, you might encourage farmers not to prevent it, which they have a lot of power to do themselves.

Mr. HARMAN. Precisely.

Mr. GLICKMAN. So at this stage I am a bit—other than establishing a much greater research component and trying to standardize testing in this country, which I think there is a crying need for some regularity and standardization of testing, I am just not sure at this stage what else we can logically do.

I would like to do more, but I don't know, maybe Mr. Jontz—I am a cosponsor of his bill and I want to do the right thing, but I want to make sure we are doing something that is sensible, not just to do something to do it, but that it has some sensible implications to it. I yield to my colleague.

Mr. JONTZ. Well, I appreciate the dilemma that the chairman finds himself in in how to design an indemnification program that works effectively is more difficult, I think, in talking about corn producers than it is maybe in talking about peanuts.

If I understand the GAO study, we don't know how many producers would seek indemnification. Our proposal was designed with the theory that getting dangerous corn off the market as quickly as possible was a good idea. Maybe that isn't so important. Maybe the blending that occurs or what have you, is something we ought to accept and maybe there is no reason to get dangerous corn off the market.

At the present time, absent the Disaster Program, whether there is incentive for the producer to dispose of the grain or whether what we are doing is forcing people to get it into the system in a way that could have adverse consequences, that since the question that is clear in my own mind, but I think that is what we need to look at. And, obviously, we could indemnify people at some rate less than market value that would be relatively minor cost, if that is a concern in terms of the behavior of the producer.

Mr. GLICKMAN. The other thing is to make sure that aflatoxin contamination is insurable under Federal crop insurance, which if it were and the program were set up adequately, it would have theoretically the same effect as being in a Disaster Program.

Mr. JONTZ. Maybe we should ask Mr. Harman and Dr. Phillips, do you think it is desirable public policy to get dangerous aflatoxin contaminated corn——

Mr. GLICKMAN. Are you still beating your wife, too? I want to know that.

Mr. JONTZ. I should say maybe to indemnify for that purpose or does the natural—the system as it now functions, works to everybody's satisfaction or do we know?

Mr. HARMAN. Well, our work has shown, first of all, that there is very little that had to be destroyed in the 1988 crop. Of course, blending did have something to do with that. Obviously, I would prefer as a consumer that we not have any dangerous food of any sort.

I mean, that is what we all should be looking for, but then there is a tradeoff between cost and benefits with that. The chairman mentioned crop insurance, and that is something we have done a great deal of work in over the years and have testified before other subcommittees of the Agriculture Committee several times.

I think that is an issue that needs to be dealt with, addressed, and perhaps this would fall under that, but there is a lot of improvement that has to be made in that program before any corn farmer is going to feel comfortable with taking out crop insurance to protect him against aflatoxin contamination, and of course, then you have the whole question. Can crop insurance work as long as you have disaster payments?

As most things in this area, it is not a simple answer, and they all seem to interrelate, and I think our position just as far as indemnification goes at this point, as the chairman stated, we still think there is a lot of information that needs to be gathered and a great deal that needs to be done before that kind of program could be implemented.

I think it needs to be considered along with crop insurance, along with things like the Conservation Reserve Program, which could be impacted if an indemnification program would encourage farmers to somehow increase production on marginal land which could somehow weaken the corn and cause some—if there is a drought, cause additional problems.

Mr. GLICKMAN. But theoretically a well-designed crop insurance program ought to include aflatoxin and contamination; is that a fair statement?

Mr. HARMAN. That's correct. Absolutely.

Mr. GLICKMAN. Well, do you have some comment on this?

Ms. RASMUSSEN. The crop insurance program now does cover aflatoxin. It is a cause of loss.

Mr. GLICKMAN. Yes. But we have other reasons why the people don't go into it for other reasons?

Mr. ZADJURA. For aflatoxin, Mr. Chairman, we have had three outbreaks in 12 years, and they are sporadic, and to expect a majority of corn farmers to buy crop insurance for something that happens once in a while and is not very widespread, even in areas where a lot of people perceive had the problem, only a small amount of corn was found to have it.

The average for the State exceeded 21 parts per billion, but 65 percent of the State crop had zero.

Mr. GLICKMAN. I understand that, but Uncle Sam doesn't have the money any longer, and that is the purpose of crop insurance, people buy it to protect themselves against these risks. Your house never burns down, but you buy homeowners insurance every single year.

That is just the way of the world. Somehow we have to design these programs to make people feel comfortable about insuring

their crop against all risks. We haven't been able to come up with an actual formula yet.

Mr. JONTZ. If the gentleman would yield, of course the problem is that you lose 25 percent of your crop to aflatoxin. You don't get $1 back.

Mr. GLICKMAN. That is because the way the program has been set up.

Mr. JONTZ. That's right, but if our concern is what are we going to do to get bad corn off the market, crop insurance wouldn't work if you have coverage at the 75 percent level because you are not going to get a thing for that first 25 percent of your crop, and I guess that is, as you say, an underlying problem with crop insurance.

Mr. ZADJURA. It was advantageous for most farmers to sell their crop even at reduced size of the crop rather than claiming a loss, and at discount levels in some cases because the drought gave us a much smaller crop, corn prices were higher than they had been in years, so they actually made more money and they really couldn't—the crop insurance or the disaster payments couldn't compete.

You were better off selling your crop. You made more money in corn's case.

Mr. GLICKMAN. We appreciate your testimony. This has been useful. We will await the final report from the GAO.

Mr. HARMAN. Thank you, Mr. Chairman.

[Whereupon, at 4:40 p.m., the subcommittee adjourned, subject to the call of the Chair.]

[Material submitted for inclusion in the record follows:]

STATEMENT ON AFLATOXIN
Congressman Lane Evans

HOUSE AGRICULTURE SUBCOMMITTEE
ON WHEAT, SOYBEANS, AND FEED GRAINS

April 2, 1990

Mr. Chairman, I am pleased to be here today to discuss the problems presented by aflatoxin in corn. This is an issue of concern to both consumers who want to be assured of the safety of the food they eat and farmers who want to supply the best possible product for those consumers. Unfortunately, rather than assisting farmers in meeting the goal of a healthy product, Federal government policy has done little more than frustrate and confuse farmers.

As you may know, portions of my district in West Central Illinois have had the misfortune of experiencing three straight years of drought. These conditions have resulted in a greater than normal amount of aflatoxin contaminated corn. To illustrate the frustration of farmers in my district in dealing with this problem, I would like to relate several of their experiences during last year's harvest.

One farmer described to me how his truck load of grain was rejected by the local elevator when their testing equipment measured it at 40 parts per billion (ppb) of aflatoxin. However, when he brought the same grain back to the elevator the next day, it tested at less than 20 ppb and the elevator accepted the grain. I understand this happened to a number of people.

In another case, a farmer, whose crop consistently showed a higher than 20 ppb level of aflatoxin at the elevators, sent a sample to a certified laboratory for testing, a requirement for crop insurance claims. When that sample came back reporting a level of less than 20 ppb, the farmer was told to submit a sample that seemed likely to have a higher level of aflatoxin.

At this point in the harvest, laboratory testing was taking three weeks. Farmers had little choice but to hold the contaminated corn while they awaited test results. I understand that aflatoxin grows rapidly in improperly dried corn so this situation could have only exacerbated any existing problem.

In addition, there was confusion on the proper disposal of corn that had above 300 ppb of aflatoxin. Should it be burned; should it be buried?

In response to the many requests from the farmers in my district, who were totally frustrated and disgusted with the situation they faced, I asked the United States Department of Agriculture to dispatch personnel to the area to perform certified laboratory testing. I received a response from Assistant Secretary for Marketing and Inspection Services Jo Ann R. Smith which said, "Let me assure you that the USDA agencies are aware of the problems and stand ready to assist your producers." However, no additional personnel was ever sent to the region and farmers were left to deal with the situation as best they could.

Needless to say, I strongly support Congressman Jontz's bill, H.R. 2641. It would provide for indemnification at full market value for grain about 300 parts per billion of aflatoxin and require the Secretary of Agriculture to establish standards for aflatoxin testing, as well as standards for the safe handling, storing and disposing of contaminated corn.

Although we all hope another drought will not occur, we have no control over a lack of rain. We can, however, help farmers minimize economic and physical damage to their crop while protecting the nation's food supply.

The farmers of America make every effort to produce the safest, highest quality product for consumers. It is the responsibility of the federal government to see that they have every assistance in achieving this goal.

United States General Accounting Office

GAO Testimony

For Release
on Delivery
Expected at
3:00 p.m. EDT
April 2, 1990

# Observations on Aflatoxin Detection and Control Activities of Federal, State, and Private Organizations

Statement of
John W. Harman, Director
Food and Agriculture Issues
Resources, Community, and Economic
Development Division

Before the
Subcommittee on Wheat, Soybeans, and
Feed Grains
House Committee on Agriculture

GAO/T-RCED-90-60

GAO Form 160 (12/87)

Mr. Chairman and members of the Subcommittee:

We are pleased to be here today to discuss the preliminary results of ongoing work we are doing at your request on aflatoxin -- a naturally occurring toxin produced by a common fungus on crops such as corn and peanuts. You asked us to develop information on (1) the relative food safety risk of aflatoxin, (2) methods for detecting and controlling it, and (3) the extent of aflatoxin in the U.S. corn crop.

In summary, our work shows that (1) food safety experts consider aflatoxin a serious food safety concern but do not consider it as serious as other food safety risks and the Food and Drug Administration (FDA), the principal agency that regulates aflatoxin in food and feed, considers the overall food supply to be safe from aflatoxin; (2) aflatoxin detection and control occurs through the collective efforts of various federal, state, and industry groups; and (3) information is inadequate to determine the extent of aflatoxin in the U.S. corn crop.

## AFLATOXIN IS NOT AS SERIOUS AS OTHER FOOD SAFETY RISKS

Aflatoxin can enter the food supply directly in products such as peanut butter, corn meal, and corn grits. Less potent forms of aflatoxin can enter the food supply indirectly in the milk, meat, or eggs of animals that eat aflatoxin-contaminated feeds. Crops are more susceptible to aflatoxin contamination when stressed by drought conditions like those experienced in the midwest in 1988

and in parts of Illinois and Texas in 1989. Aflatoxin was subsequently found in corn grown in those areas.

Although the presence of aflatoxin in food products is undesirable, aflatoxin is not considered as serious as other food safety risks. Although there is no precise way to rank food safety risks, experts like FDA and the American Association of Cereal Chemists generally rank microbial contaminants such as salmonella and listeria as the major health hazard associated with food because of their potential to kill humans after one exposure. Malnutrition -- the consumption of an improper mix of nutrients, excessive amounts of fats and salts, etc. -- and environmental contaminants such as lead and mercury are also considered more serious than aflatoxin. Pesticide residues and additives are usually ranked as less serious than aflatoxin.

Because aflatoxin occurs naturally and cannot be entirely eliminated, FDA allows small amounts, referred to as action levels, to be present in foods and feeds. FDA set the action levels at 20 parts per billion (ppb) for food, 0.5 ppb for milk because infants and children drink large quantities, and varying levels up to 300

ppb for feeds.[1] If aflatoxin exceeds these levels, FDA considers whether action is needed to control the contaminated product.[2]

Although FDA's surveillance sampling of corn-based products has shown a small number of instances where aflatoxin made its way into consumer channels at levels exceeding regulatory limits, FDA does not consider the food supply to be at risk. At fiscal year 1990 hearings before the Subcommittee on Rural Development, Agriculture and Related Agencies of the House Committee on Appropriations, the FDA Commissioner said that FDA was confident that there was no risk associated with the commercial food supply as a result of the 1988 drought. He stated that occasional consumption of the very few corn products that contain small amounts of aflatoxin is of little lifetime health consequence, because only repeated exposure to relatively high aflatoxin levels over a number of years presents a significant safety risk.

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[1]Higher levels of contamination in feed are allowed because research has shown that animals, depending on their size, maturity, or whether they are used for breeding stock, can eat higher levels of aflatoxin without ill effects.

[2]In 1987, the United States Court of Appeals for the District of Columbia Circuit found that action levels, because they were not established through the notice and comment procedure of the Administrative Procedure Act (5 U.S.C. 553) were not legally binding and that FDA had to establish new regulatory limits through the notice and comment process. Until FDA establishes new limits it must prove on a case-by-case basis that the amounts of aflatoxin in a food "may be injurious to health' in order to take regulatory action such as seizing the product. Thus, FDA is now in the process of establishing new regulatory limits.

FDA's surveillance activities -- which increased significantly in 1989 because of the drought -- showed that a small percentage of food products exceeded the action levels. Between October 1988 and June 1989, FDA sampled 2,097 food products and found that 5.5 percent of the whole corn shipments and 2.2 percent of the milled corn products contained aflatoxin in excess of the 20 parts per billion limit. The products in which aflatoxin was found would have to be further processed or prepared which would further reduce the aflatoxin levels before they were eaten.

In comparison, for fiscal year 1986 (not a midwest drought year), FDA sampled about 300 food products and found a slightly higher incidence of aflatoxin than in fiscal year 1989 (6.8 percent of the whole corn samples and 4.3 percent of the milled corn products had levels exceeding 20 parts per billion). FDA said that the 1986 and 1989 sample results were biased towards geographic areas suspected of having aflatoxin and firms with a prior history of Food and Drug Law violations.

AFLATOXIN DETECTION
AND CONTROL EFFORTS

Testing for aflatoxin, particularly for corn, is difficult because of the large volume of grain involved (about 8 billion bushels annually) and because of testing problems. Obtaining representative samples is a problem at all of the about 8,000 locations where whole corn is traded--including whole corn deliveries at mills because, (1) aflatoxin is concentrated in individual kernels of corn, (2) infected kernels may not be evenly

distributed through a bulk lot, (3) there are differences in the aflatoxin level of individual kernels, and (4) aflatoxin is measured in exceedingly small quantities.

Only about 16 percent of the annual corn crop (about 1.2 billion bushels) is used for human food and most of that is processed at about 100 mills. Sample variability is less of a problem after corn has been milled because it has been ground and mixed, and any aflatoxin in it is more evenly distributed. Consequently, representative samples are more easily obtained.

Further, testing all corn marketed, including that used for commercial feed, will not always ensure that aflatoxin will be eliminated from the food supply. While recent USDA research shows that the meat, poultry, and eggs from animals eating aflatoxin are not likely to be a food safety threat, the milk from dairy cows fed aflatoxin contaminated feeds can contain aflatoxin residues in excess of FDA's action levels. Contaminated milk has been traced to both commercial feeds and those grown and fed on farms.

Despite these difficulties, aflatoxin detection and control occurs through the efforts of various federal, state, and private groups. Each organization has its own testing objectives such as assuring food safety, market efficiency, and profitability.

FDA does not monitor all affected foods and feeds for aflatoxin. Instead, FDA requires food and feed manufacturers to follow regulations commonly referred to as good manufacturing practices. These regulations require food processors to have quality control procedures that ensure food products are safe, wholesome, and suitable for human consumption. Manufacturers are required to use only raw materials and ingredients that are within FDA's action levels. Manufacturers may either purchase ingredients that are guaranteed or certified to be within the action levels or may test the ingredients themselves. As I mentioned, FDA annually samples a small number of susceptible raw materials and food products to monitor industry compliance with its regulations and obtain data on the level and frequency of aflatoxin contamination.

Food manufacturers and firms that mill corn, shell peanuts, or otherwise prepare raw commodities used in food manufacturing contribute to aflatoxin detection and control and have economic incentives to do so as part of their quality control procedures.

One food manufacturing company's quality control director told us his company requires its suppliers to have quality control systems that ensure products are within FDA's action levels. At the onset of the 1988 harvest, his company reviewed its suppliers' sampling and testing program and required some suppliers to make changes to satisfy his company's requirements. Subsequently, the

manufacturer implemented a program to sample and test dry milled[3] products for compliance. The manufacturer did not focus on wet milled[4] food products because research has shown that most of the aflatoxin is removed during the wet milling process.

Although we did not determine the extent of industrywide testing, milling trade association officials told us that aflatoxin testing has been standard procedure in their industry for years. An official of a dry milling industry organization said current industry efforts may involve testing of whole corn as it is delivered to plants or removed from storage for processing, as well as testing of finished products. An official of a wet milling organization said that, in favorable growing years, a statistical sampling plan may be used to determine the extent of testing needed. Testing is increased as the corn crop enters the market so that companies can identify and avoid geographic areas producing aflatoxin-contaminated corn. During the drought, testing was increased to cover all incoming corn.

At the federal level, FDA works with other federal agencies to extend its monitoring of susceptible commodities. The principal federal agencies with whom FDA works are USDA's Agricultural Marketing Service (AMS) and USDA's Federal Grain Inspection Service

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[3]Dry milled products include corn meal, corn flour, grits, alcohol, and corn oils for human use, and animal feeds.

[4]Wet milled products include starches, sugars, oils, and animal feeds.

(FGIS). AMS oversees a peanut marketing agreement that requires all peanuts sold by farmers to be sampled and visually inspected for the mold that produces aflatoxin, and all peanuts, before they are sold to food manufacturers, are sampled and tested for aflatoxin. Unlike the peanut program, FGIS's sampling and testing of grain and grain products is on a request basis.

At the state level, aflatoxin detection and control activities vary with state interests and for reasons such as the frequency of aflatoxin's occurrence. For example, some states, such as Georgia and North Carolina, have annual programs to monitor susceptible food and feed products for aflatoxin. They, and other states, assist the AMS by providing inspectors to carry out the detection and control program for peanuts. In other states, aflatoxin control activities are less extensive.

FDA coordinates with states to avoid duplication and, to the degree that FDA has confidence in a state's control efforts, FDA limits its activity to spot checks. FDA shares its aflatoxin surveillance results with state regulatory agencies and encourages them to reciprocate. In this way, FDA supplements its information on the extent of aflatoxin in food and feeds.

## INFORMATION ON THE EXTENT OF AFLATOXIN IN CORN IS LIMITED

Information on the incidence of aflatoxin in the corn crop is inadequate for determining whether aflatoxin is a widespread problem. Although individual states monitor field corn for

aflatoxin their results do not show how widespread aflatoxin is because state surveys may not be done in a statistically reliable manner. Generalizations about the incidence of aflatoxin are difficult because aflatoxin is a localized problem even in years of widespread drought. For example, one state study showed that although the average level of aflatoxin in the state's crop was 21 parts per billion, 65 percent of the crop had no detectable level of aflatoxin. However, limited state testing results are sometimes reported by the media as estimates of the extent of aflatoxin for the entire state without recognizing the limitations of the state study or the variability of aflatoxin across the state.

A recent proposal by the Iowa Aflatoxin Task Force -- consisting of representatives from state government, producer organizations, grain trade, and academia -- offers a proactive approach to gathering additional information on the occurrence of aflatoxin in the corn crop. The proposal calls for (1) a pre-harvest weather monitoring and early warning system to predict high-, medium-, and low-risk areas of aflatoxin formation and (2) physical sampling at harvest time to confirm or deny advance warning data. It is intended to alert regulators and the grain industry to the possibility of aflatoxin contamination and reduce its impacts by allowing (1) FDA and state regulators to focus their aflatoxin control efforts on locations with the highest risk; (2) dairy farmers to decide whether the feeds they grow or purchase

should be tested for aflatoxin; and (3) food processors to select locations from which to purchase their raw ingredients.

USDA's National Agricultural Statistics Service (Service) would, according to the Iowa proposal, establish risk areas using temperature and moisture information reported by the State Crop Reporting services. Some additional research would be required to develop specific criteria for relating weather information to aflatoxin formation. Sampling to substantiate advance warning data would be accomplished by modifying the Service's existing at-harvest crop sampling program. Adding aflatoxin testing would require that larger samples be drawn, dried immediately to stop further aflatoxin formation, and then sent for laboratory analysis. Since the Service relies on farmer cooperation for its surveys, it has turned down earlier requests to estimate aflatoxin in corn because it is a controversial issue with farmers, and may cause the Service to lose farmer cooperation.

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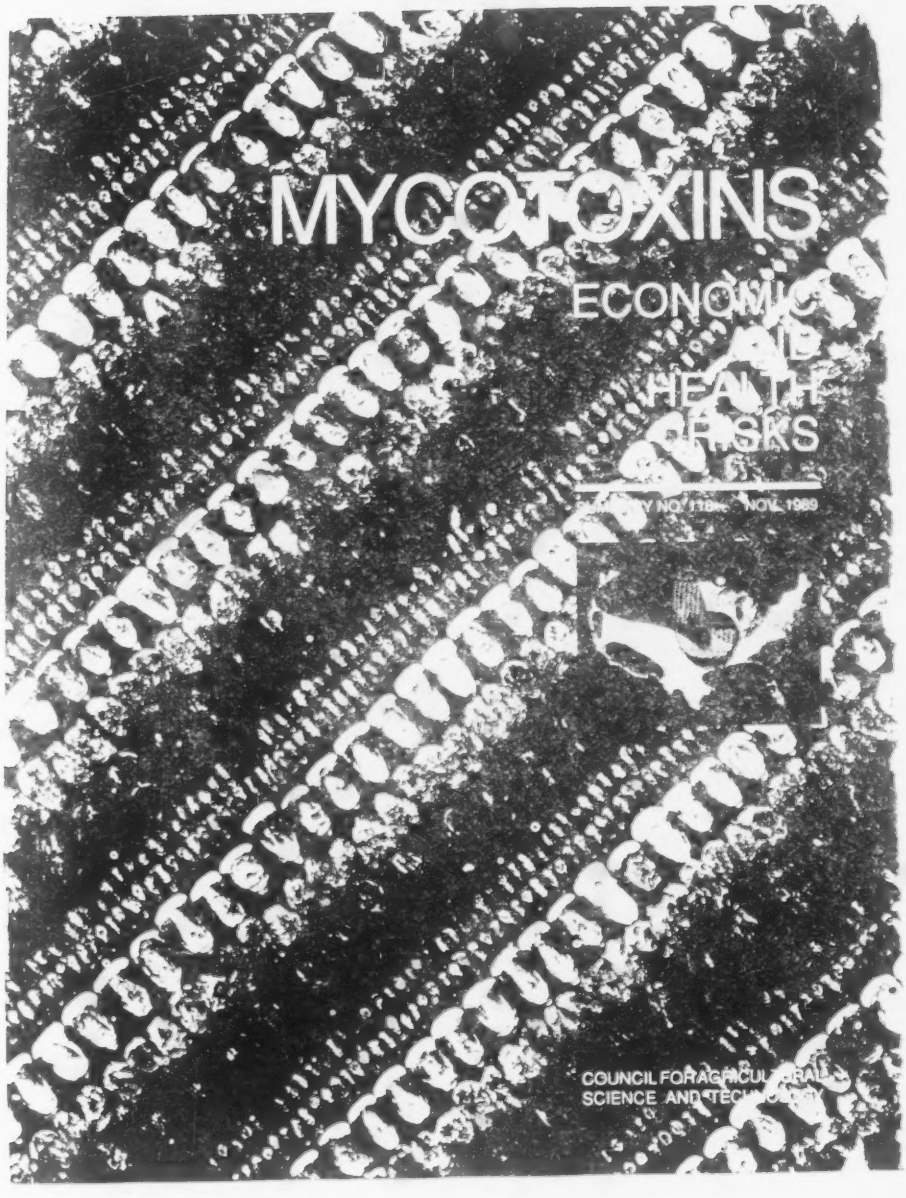
In summary, aflatoxin is a serious food safety concern, but it is not as serious as several other food saftey risks. An infrastructure of federal, state, and industry groups exist to test and control the incidence of aflatoxin in the overall food supply. At this time, FDA considers that supply to be safe from aflatoxin. Nevertheless, the adequacy of testing procedures and whether additional testing is needed continues to be controversial, particularly for the corn crop, and proposals have been made to

increase testing. If it is decided more testing is necessary, a logical point for additional testing is the approximately 100 mills where corn is processed into food. This is at the point of greatest risk. The Iowa Aflatoxin Task Force's proposal also offers one approach for making this testing and control process more proactive and thereby possibly improving monitoring of aflatoxin.

Mr. Chairman, this ends my prepared statement. I would be glad to respond to any questions.


MYCOTOXINS
ECONOMIC
AND
HEALTH
RISKS
NOV. 1989
COUNCIL FOR AGRICULTURAL
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# Council for Agricultural Science and Technology

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# Foreword

A request for an update of the 1979 CAST task force report on aflatoxins was received in February 1988. Since 1979, many additional mycotoxins have been discovered and new problems have been associated with certain mycotoxins. There is considerable recent information regarding occurrence, toxicity, epidemiology, detection, analysis, economic impacts, and control and management of mycotoxins.

The CAST National Concerns Committee recommended to the Board of Directors that CAST prepare a more comprehensive report addressing the entire area of mycotoxins. This topic was approved by the CAST Board of Directors at the February 1988 board meeting.

Nominations for the task force members were received from the representatives of the CAST Board of Directors. Two cochairs with expertise in complimentary areas were selected, John L. Richard, whose research is on effects of mycotoxins on animal health, and Richard J. Cole, who is associated with mycotoxin research on an important commodity (peanuts). A highly qualified and broad based task force of scientists was chosen that includes persons with expertise in such diverse fields as plant pathology, toxicology, chemistry, economics, human health and medicine, veterinary medicine, microbiology, engineering, and contaminants regulations. Additionally, three scientists from industry agreed to serve as technical advisors and are included herein as part of the task force. Another eight scientists also contributed to various sections of the report.

Drs. Richard and Cole proposed an outline of the subject matter and submitted it to the task force prior to the task force meeting held in Kansas City in July 1988. At the meeting, the members reached a consensus on the scope of the report, developed a detailed outline, established a calendar of completion dates for the first and second drafts of the report, and selected subgroups (each with a chair) to be responsible for writing the chapters of the report. The entire task force revised each draft of the report and reviewed the proofs. The CAST Executive and Editorial Review Committees reviewed the final draft. The CAST staff provided only editorial and structural suggestions. The cochairs and task force are responsible for all scientific content in the report.

During the latter part of 1988 and throughout 1989, task force members were spending considerable time investigating problems associated with mycotoxin contamination of grain crops in the United States caused by the 1988 drought. The public, government agencies, and others were aware that CAST was producing a report on mycotoxins and CAST received many inquiries regarding the problems. CAST had recently organized this task force and was able to refer the callers to the cochairs and members of the task force, who readily provided assistance.

On behalf of CAST, we thank the task force members, who gave of their time and talents to prepare this report as a contribution of the scientific community to public understanding. We thank also the employers of the task force members, who made the time of the members available at no cost to CAST. The members of CAST deserve special recognition because the unrestricted contributions they have made in support of the work of CAST have financed the preparation and publication of this report.

This report is being distributed to members of Congress, the Food and Drug Administration, the Environmental Protection Agency, the U.S. Department of Agriculture, the Office of Technology Assessment, the Office of Management and Budget, and the Agency for International Development, to media personnel, and to institutional members of CAST. All individual members of CAST receive a summary of the report and may order a copy of the full report. The report may be republished or reproduced in its entirety without permission. If copied in any manner, credit to the authors and CAST would be appreciated.

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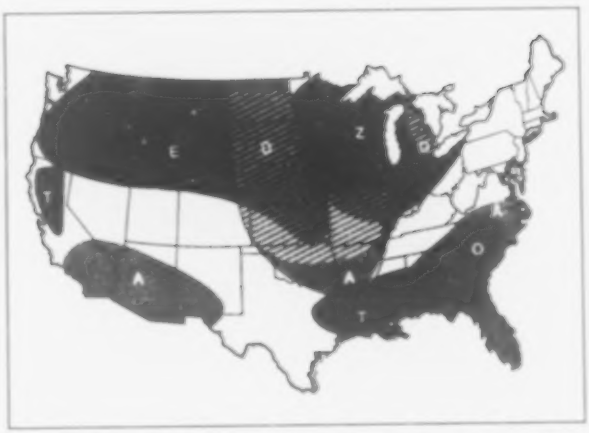


Major mycotoxins associated with field crops by general geographic areas in the United States.

A = aflatoxins
D = deoxynivalenol
E = ergot
O = ochratoxin A
T = tremorgens
Z = zearalenone

Courtesy of A. C. Pier and J. L. Richard.
Cover design and art work by L. Ekblad, Chichaque Bend Studios, Ames, Iowa

# Mycotoxins: Economic and Health Risks

## Introduction

Toxic fungal metabolites, known as mycotoxins, are chemically diverse, occur in a wide variety of substrates including foods and feeds, and can cause both economic and health losses for humans and animals through disease and reduced efficiency of production.

The fungi that produce mycotoxins can invade the food and feed supply during production, processing, transport, or storage. These fungi may be pathogenic to plants or saprophytic. The three major genera of mycotoxin producing fungi are *Aspergillus*, *Fusarium*, and *Penicillium*. Several factors influence mycotoxin production by fungi, including substrate, moisture, temperature, pH, and stresses such as drought and associated growth of other fungi or microbes. The major crops affected in the United States are corn, peanuts, and cotton.

## Mycotoxins and Animal Health

Mycotoxins can produce a wide range of potential injury to animals, in addition to being food borne hazards to humans. The economic impact of reduced productivity, increased disease incidence because of immune suppression, subtle but chronic damage to vital organs and tissues, and interferences with reproductive capacity is estimated to be many times greater than that of livestock death.

The aflatoxins can cause liver damage, decreased milk and egg production, and suppression of immunity in animals consuming low dietary concentrations that do not cause overt disease. While the young of a species are usually most susceptible, all ages are affected, and typical clinical signs are gastrointestinal dysfunction, reduced reproductivity, decreased feed utilization and efficiency, anemia, and jaundice. Nursing animals may be affected by exposure to aflatoxin metabolites secreted in the milk.

The trichothecene mycotoxins are a large group of mycotoxins that cause necrosis and hemorrhage throughout the digestive tract, depress blood regenerative processes in the bone marrow and spleen, and cause changes in reproductive organs. Affected animals show signs of weight loss, poor feed utilization, apparent inappetence, vomiting, bloody diarrhea, abortion, and death. Suppression of immunity is a significant feature of certain trichothecene mycotoxins.

Ochratoxin A damages the kidneys of a wide variety of domestic and wild animals that consume contaminated feed. High concentrations of dietary ochratoxin A can also cause liver damage as well as intestinal necrosis and hemorrhage. Ochratoxin A has been shown to suppress immunity and to be carcinogenic.

Zearalenone mimics the effects of the female hormone estrogen and induces feminization at dietary concentrations of less than 1 ppm, while higher concentrations interfere with conception, ovulation, implantation, fetal development, and the viability of newly born animals.

A variety of other effects have been attributed to mycotoxins. Embryonic death, inhibition of fetal development, and abortions have been associated with ergot, aflatoxins, rubratoxin, and zearalenone in the rations of pregnant animals. Teratogenicity has been documented in at least one mammalian species for aflatoxins, ochratoxin, rubratoxin, T-2 mycotoxin, zearalenone, and sterigmatocystin.

Nervous system functions are adversely altered by at least nine mycotoxins. Clinical signs include tremors, uncoordinated movements, weakness of one or more limbs, staggering, and sudden muscular collapse from the consumption of contaminated forage, silage, cereal grains, or dietary supplements. In some instances, the neurological effects are complicated by seizures, diarrhea, hemorrhage of the digestive tract, profuse salivation, feed refusal, and gangrene of the limbs, ears, or tail.

At least three mycotoxins (aflatoxins, ochratoxins, and sterigmatocystin) are known to induce tumors in one or more species of animal. The cancers have developed in liver, kidney, urinary system, digestive tract, and lung. The unique effects of some mycotoxins in producing skin irritations on contact and causing direct death of nervous tissue in the brain highlight the sensitivity of selected organs in certain species to these unique toxins.

The range and potency of mycotoxins in causing damage in animals make this group of naturally occurring toxins an ongoing animal health hazard and a constant risk for contamination of the food supply.

## Mycotoxins and Human Health

Humans are exposed to mycotoxins by consuming foods contaminated with fungal growth. Such exposure is unavoidable because there are finite limits to the extent that fungal growth can be prevented in foods.

Some of these mycotoxins have been shown to have potent acute and chronic biological activities as determined in animal studies and *in vitro* bioassays.

Consumption of foods heavily contaminated with mycotoxins has resulted in acute toxicity episodes in human populations. Conditions increasing the likelihood of such occurrences include limited food supply, environmental conditions that favor mycotoxin formation, and the absence of effective mycotoxin monitoring and control systems. These conditions, for the most part, appear to be limited to certain areas in developing Asian and African countries.

Such occurrences in the United States are unlikely because heavily contaminated and uncontrolled food does not normally exist. Concern still remains for possible adverse effects resulting from long term exposure to low levels of mycotoxins in the food supply.

The major concern has focused on the possible contribution of aflatoxin exposure to the development of liver cell cancer (LCC). The assessment of possible adverse effects resulting from long term low level exposure to aflatoxins is a difficult task due to methodological problems and uncertainties inherent in the currently available data and evaluation procedures.

Despite these uncertainties, several significant findings have been reported. Some human population studies conducted in Africa and Asia have reported positive correlations between the estimated degree of aflatoxin exposure and incidence of LCC. Although complete investigations have not been conducted in the United States, there is no apparent association between aflatoxin consumption and LCC. Studies conducted in other countries have yielded mixed results.

Additional information suggests that certain other alternate risk factors for human LCC (e.g., hepatitis B virus) may play an important role in determining the relative susceptibility of humans to the suspected effects of aflatoxins. This information has complicated defining the role of aflatoxins in human LCC risk. When considered in a "weight of evidence" approach for safety evaluation, it suggests that in the United States, aflatoxins may not be as important of a risk factor for human LCC as might be inferred by the epidemiological studies conducted in Africa and Asia.

Techniques are under development to strengthen future human population studies by increasing the confidence in estimates of aflatoxin exposure. These techniques focus on human biological monitoring for aflatoxin exposure.

Our current system of mycotoxin monitoring and control must be maintained to assure that exposure to mycotoxins in the United States remains low.

## Occurrence of Mycotoxins in Foods and Feeds

Many foods and feeds can be contaminated with mycotoxins before harvest, during the time between harvesting and drying, and in storage. A few mycotoxins, such as those associated with ergotism, are produced exclusively in the field. Many other mycotoxins can contaminate crops before harvest and, under certain circumstances, progressively increase from that point. Aflatoxins, produced by *Aspergillus flavus* and *A. parasiticus*, can be found in the field before harvest and contamination can increase during post harvest activities such as crop drying or in storage. In addition, the aflatoxins can subsequently contaminate stored products in the absence of field contamination. Many other fungi that produce mycotoxins contaminate crops in much the same way.

With the exception of the aflatoxins, the frequency of contamination of feeds and foods by other mycotoxins is not known. Aflatoxins have been detected in milk, cheese, corn, peanuts, cottonseed, brazil nuts, copra, almonds, pecans, figs, spices, and a variety of other foods and feeds. Corn, peanuts, and cottonseed are the most frequently analyzed domestic crops, while copra, pistachio nuts, brazil nuts, figs, and spices are of concern in imported products. Milk, eggs, and meat products can possibly be contaminated because the animal has consumed mycotoxin contaminated feed.

Besides the aflatoxins, the ochratoxins and the *Fusarium* produced mycotoxins have received the greatest attention as contaminants of foods and feeds. These mycotoxins tend to occur in the more temperate regions of the United States. Zearalenone and deoxynivalenol are more of an economic concern to animal producers in the United States than ochratoxin. Many other mycotoxins, produced by various *Aspergillus*, *Penicillium*, *Fusarium*, and *Alternaria* species can contaminate products, and the incidence and relative importance to animal and human health of these different mycotoxins has not been established.

Because mycotoxin contamination of foods occurs in a random manner, a mycotoxin free food supply can not be guaranteed. The ability to identify and remove all naturally occurring mycotoxin contamination or even all of a specific mycotoxin from foods and feeds is limited. Thus, it is important to establish realistic goals for mycotoxin management.

## Economic Impacts of Mycotoxins

It is estimated that one quarter of the world's food

crops are affected by mycotoxins annually. Mycotoxins and their control impose discernible economic costs on United States crop, livestock, and poultry producers, grain handlers, and food and feed processors. The economic impacts of mycotoxins are derived directly from crop and livestock losses, as well as from regulatory programs designed to reduce risks of exposure to animals and humans (Table 1). Yet, despite the recognized economic impact of mycotoxins, we are unable to quantify losses adequately.

The incidence of mycotoxins in the United States varies among commodities, years, and regions. Years of extreme drought and other environmental conditions favorable to aflatoxin development are more likely to result in higher economic losses, although even then, losses may occur randomly, making prediction and aggregate cost estimates difficult. Although mycotoxins are naturally occurring chemicals, mycotoxin levels are potentially affected by economic as well as environmental factors, including choice of mechanical harvesting technology, relative prices of insecticides, fungicides and labor, and agricultural price supports.

The crops most affected economically in the United States are corn, peanuts (including peanut meal), cottonseed, and cottonseed meal. Cottonseed grown in the Southwest and corn in the Southeast are more frequently affected than in the Midwest. Annually, less than 2% of the total U.S. corn production is affected economically, yet losses for individual producers can be significant. Peanuts in all growing regions can potentially incur economic losses attributable to aflatoxin. Losses can also occur in corn and animal products such as cornmeal, grits, milk, and eggs. Theoretically, other fruits and vegetables can be affected, but no economic losses have been documented. Effects on products of fermentation (e.g. beer, wine, and fruit juices) do not appear to be an economic problem in the United States.

Mycotoxins produce a wide range of adverse economic effects, including lower yields for food and fiber crops. Mycotoxin losses to livestock and poultry producers

Table 1. Types of economic losses and costs associated with contamination of foods or feeds by mycotoxins as expressed in general terms (adapted from Jemmali, 1987*)

| Bearer of economic losses and costs | Economic losses and costs |
|---|---|
| National level | |
| Primary producer | Outright food and feed loss |
| | Contaminated crops provide less income and may lead to potential loss of outlet |
| | Reduced productivity of livestock from (1) lower quantity and quality of animal products, (2) smaller litters, (3) reduced work output, (4) loss of pregnancy, (5) reduced feed efficiency, (6) impaired resistance to disease, and (7) loss of vaccination efficacy |
| Intermediary | Less income from products refused, condemned, or sold at discount |
| | Increased storage, transport, and packing costs on such products |
| | Potential loss of market, trading reputation, and raw material source |
| | Increased costs due to litigation (may exceed cost of product) |
| | Increased costs due to surveillance and control |
| National government | Lower foreign exchange earnings from reduced exports |
| | Increased costs involved in shipment, sampling, and analysis of exported goods that are subsequently refused import entry; potential loss of overseas outlets |
| | Increased costs of detoxification or reconditioning abroad |
| | Increased costs for food or feed imports, staple food subsidies |
| | Increased costs of surveillance and control |
| | Increased need for expenditures on human and animal health facilities and activities |
| | Increased costs involved in training and extension programs |
| Consumer (human or animal) | Consumption may lead to impaired health and productive capacity |
| | Lack of food may lead to undernutrition or higher food prices resulting from outside purchase of foods or feeds |
| | Possible medical and veterinary costs associated with the above conditions in previous two statements |
| | Possible consumer-initiated litigation costs |
| International level | Inconsistent supply resulting in price fluctuation and loss of market |
| | Increased difficulty involved in arriving at sound international agricultural production adjustments and commodity and food security agreements |

*Jemmali, M. 1987. *Trade and economic implications of mycotoxins: Need for greater uniformity.* Report No. 6. Working paper presented at the Second Joint FAO/WHO/UNEP International Conference on Mycotoxins, Bankok, Thailand, September 28 to October 3, 1987.

from mycotoxin-contaminated feeds include death and the more subtle effects, among them, immune suppression, reduced growth rates, and losses in feed efficiency. Prices are often lower for animal products and higher for feeds, and regulations can restrict the use of food and feed crops when acceptable levels are exceeded. The economic result is that output is reduced, production costs are increased, and returns to growers are reduced. Costs to consumers can include higher product prices in years of severe outbreaks and increased health risks when regulations fail.

Social costs to control mycotoxins include regulatory enforcement expenses, in addition to research and extension efforts. Economic losses are inextricably linked to regulatory standards. Food and Drug Administration (FDA) guidelines are conservative to assure that risks are minimal, but flexibility exists to balance health risks with an adequate food and feed supply. To this end, exemptions to guidelines have been made on a case by case basis when market disruption is threatened by widespread aflatoxin incidence. Although this policy of restricting known carcinogens to the lowest feasible level is consistent with regulations governing other food constituents, there is ongoing scientific and policy debates regarding the appropriateness of these levels.

International regulatory standards have critical economic implications. More stringent standards result in higher costs for producers and exporters, and can discriminate against developing countries. In the long run, they may lead to increased demand for commodities by ensuring consistency and quality. On the other hand, overly restrictive and inconsistent standards can introduce significant barriers to trade. Because regulatory restrictions significantly impact losses, expected benefits of these restrictions must be accurately addressed. Standards must be based on sound health-based scientific data. To this end, improved economic information on incidence and associated losses are essential. Additionally, the increase in internationally traded agricultural commodities necessitates consistent cost effective control of mycotoxins.

## Control and Management of Mycotoxins

In the United States, the aflatoxins are the only mycotoxins that are formally and specifically regulated. Aflatoxins are considered unavoidable contaminants of food and feed where Good Manufacturing Practices (GMP's) have been followed and, as such, are regulated under the Food, Drug, and Cosmetic Act (Section 402). The FDA established more specific guidelines for acceptable levels of aflatoxins in human food and animal feed (i.e., action levels) that allow for the removal of violative lots from interstate commerce (Table 2). The action levels for human food are 20 parts per billion (ppb) total aflatoxins, with the exception of milk, that has an action level of 0.5 ppb for aflatoxin $M_1$ (a metabolite of aflatoxin $B_1$). For feeds the action level for aflatoxins is also 20 ppb with the exception of a 300 ppb action level for aflatoxins in cottonseed meal used in feeds, a 300 ppb action level for corn used for finishing (feedlot) beef cattle, 200 ppb for corn destined for finishing swine (i.e., 100 lbs.), and 100 ppb aflatoxins in feeds used for breeding cattle, breeding swine, and mature poultry. However, corn in interstate shipment with a given acceptance level of aflatoxins for feeds must be used for the designated species.

To effectively monitor food and feed for a particular mycotoxin, it is important to be able to accurately estimate its concentration. However, this is very difficult to accomplish in a large quantity of material, because of the variability associated with established testing procedures. The total variability of these procedures is equal to the sum of errors associated with each step (i.e., sampling, comminuting-subsampling, and analysis of aflatoxins). Because of these errors, the true aflatoxin concentration in a lot cannot be determined with 100% certainty. The only way to achieve a better estimate of the lot concentration is to reduce the total

Table 2. U.S. Food and Drug Administration guidelines for acceptable levels of aflatoxins in food and feed

| Action level (ppb) | Commodity | Species |
|---|---|---|
| 0.5 (Aflatoxin $M_1$)* | Milk | Humans |
| 20.0 | Any food except milk | Humans |
| 20.0 | Feed | All species |
| Exceptions: | | |
| 300.0 | Cottonseed meal used in feed | All species |
| 300.0 | Corn | Finishing beet cattle |
| 200.0 | Corn | Finishing swine (< 100 lbs.) |
| 100.0 | Corn | Breeding cattle, breeding swine, and mature poultry |

* Specifically for aflatoxin $M_1$, a toxic metabolite of aflatoxin $B_1$, that occurs in milk.

variance associated with test results. The sampling variance can be reduced by increasing the sample size. The subsampling variance can be reduced by increasing the size of the subsample or by increasing the degree of comminution (number of particles per unit mass in the subsample). The analytical variance can be reduced by increasing the number of analyses.

Presently, a high degree of technical expertise and laboratory sophistication [e.g., thin-layer chromatography (TLC), gas and high performance liquid chromatography (GLC and HPLC), and GLC/mass spectrometry, etc.] are widely utilized for the detection and molecular confirmation of various mycotoxins. The development of rapid and field practical screening tests for mycotoxins (e.g., black light, minicolumns, and immunoassays) has greatly facilitated prevention through effective monitoring programs that allow for the detection and diversion of contaminated crops and animal feeds. A variety of structure-selective techniques have emerged to the forefront of research in chemistry and immunology. These include methods of selective adsorption of multi-mycotoxins (SAM) and immunoassays. The immunoassays utilize mycotoxin-specific antibodies that can discriminate between minor differences in chemical structure. A number of commercial kits (including minicolumns, SAM detectors, and immunoassays) are currently available for the field practical analysis of mycotoxins.

Although rigorous guidelines have been long established for the preventive management of aflatoxins in crops (i.e., recommended practices for growing/production, harvesting, handling, storage, processing/manufacturing, sampling, and analysis), significant contamination can still occur. It is important to understand that good crop management techniques and practical methods of aflatoxin detection (although significant tools) do not provide a complete solution, because aflatoxin contamination is unavoidable, and sampling problems may easily bias aflatoxin analyses. Consequently, the development and utilization of safe and effective procedures for the decontamination/detoxification of aflatoxin-containing food and feed would provide important additional protection from exposure to these hazardous substances.

Numerous strategies for the detoxification of aflatoxins have been proposed. These generally include methods of physical separation, thermal inactivation, irradiation, microbial degradation, and treatment with a variety of chemicals. The detoxification strategy that has received the most attention is the treatment of aflatoxin-contaminated feed with ammonia (i.e., ammoniation). The ammoniation procedure is currently being utilized in Arizona and California to reduce the parent aflatoxin levels in cottonseed products for animal feed, and in France, Senegal, and Brazil for the treatment of aflatoxin-contaminated peanut meal. Although ammoniation was apparently safe and effective in earlier studies, it has not been sanctioned yet by the United States FDA, due to the incomplete information on the potential toxicity and carcinogenicity of reaction products. A new approach to the detoxification of aflatoxins is the use of inorganic adsorptive compounds, such as hydrated sodium calcium aluminosilicate (HSCAS or NovaSil™), in the diet. These compounds possess the ability to tightly bind and neutralize aflatoxins in the gastrointestinal tract of animals. Recent studies indicate that HSCAS can reduce the adverse effects of aflatoxins in chickens and swine and decrease the level of aflatoxin M$_1$ residues in the milk of lactating dairy cattle.

A cooperative effort on the part of academia, government, and industry to identify and implement state-of-the-art integrated control and preventive management strategies to solve mycotoxin problems is clearly warranted. The effective combination of safe and field-practical tools for the detection and detoxification of mycotoxins (along with optimal methods of food and feed production, harvesting, handling, storage, and processing/manufacturing) provides an integrated approach to the preventive management of mycotoxins.

## Future Needs

Future needs in mycotoxin research include:

1. Surveillance of commodities, foods, and feeds for presence and quantity of mycotoxins.
2. Surveillance of human populations to assess the exposure level to selected mycotoxins.
3. Assessment of control methods of mycotoxins involving methods of decontamination/detoxification.
4. Development of standard regulatory controls of mycotoxins for international trade.
5. Development of resistant plants to fungal and mycotoxin occurrence.
6. Development of biocompetitive agents for toxigenic fungi.
7. Improvement of sampling and analysis for mycotoxins.
8. Research on the effect of mycotoxins on animal and human disease through immunosuppression and interaction with other disease agents.
9. Toxicological evaluation of newly discovered mycotoxins.
10. Examination of the possible therapeutic and biocontrol nature of mycotoxins.
11. An integrated worldwide assessment of the economic aspects of mycotoxins.

# Recent and Forthcoming CAST Publications

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Task force reports are CAST's principal publications. Reports are prepared by groups of eminent scientists working in various disciplines related to the subject. Task forces write reports intended to be sound statements on the scientific aspects of subjects concerning food and agriculture, and do not take positions or make policy recommendations.

**Agriculture and Groundwater Quality**
R103, May 1985, 62 pp., $5.00

**Plant Germplasm Preservation and Utilization in U.S. Agriculture**
R106, November 1985, 55 pp., $5.50

**Diet and Coronary Heart Disease**
R107, November 1985, 22 pp., $2.00

**Forages: Resources for the Future**
R108, March 1986, 70 pp., $4.00

**Ionizing Energy in Food Processing and Pest Control: I. Wholesomeness of Food Treated With Ionizing Energy**
R109, July 1986, 50 pp., $4.00

**Diet and Health**
R111, March 1987, 62 pp., $5.00

**Pests of Plants and Animals: Their Introduction and Spread**
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**Effective Use of Water in Irrigated Agriculture**
R113, June 1988, 64 pp., $5.00

**Long-Term Viability of U.S. Agriculture**
R114, June 1988, 48 pp., $4.00

**Ionizing Energy in Food Processing and Pest Control: II. Applications**
R115, June 2000, 98 pp., $10.00

**Mycotoxins: Economic and Health Risks**
R116, November 1989, $10.00

## Special Publications

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SP14, June 1985, 28 pp., $3.00

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SP15, November 1987, 13 pp., $2.00

## Comments from CAST

Timely letters and other comments of broad interest, usually written by a single author.

**Food Irradiation**
by Julius M. Coon, Edward S. Josephson, and Eugen Wierbicki
CC1985.2, March 1985, 10 pp., $2.00

**Antibiotics for Animals**
by Virgil W. Hays
CC1985.3, March 1985, 10 pp., $2.00

**Health Issues Related to Chemicals in the Environment**
by Arthur L. Craigmill, M. Alice Ottoboni, Charles C. Aller, Thomas L. Carson, Roger E. Gold, Ralph Grotelueschen, Charles S. Helling, Glen J. Hoffman, Richard A. Jackson, Terry L. Lavy, Terry J. Logan, Harry B. Pionke, and Robert C. Spear
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**Reducing American Exposure to Nitrate, Nitrite, and Nitroso Compounds: The National Network to Prevent Birth Defects Proposal**
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**Antibiotics for Animals: The Antibiotic-Resistance Issue**
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SFA1.1, Vol. 1, No. 1, September 1988, 12 pp., $1.00

**The Search for Life. BST: Biotech and the Dairy Cow. Pasta Science. Lab: Egg Pasta. Lab: Cloning African Violets.**
SFA1.2, Vol. 1, No. 2, January 1989, 12 pp., $1.00

**Top Ten Innovations in Food. So Long, Mr. Screwworm. Searching for the Seedless Watermelon. Water's Importance in Meat Processing. Water-binding Experiment. Lab: Measuring Forage Moisture.**
SFA2.1, Vol 2, No. 1, September 1989, 12 pp., $1.00

## Forthcoming Reports

Ecological Impacts of Federal Conservation and Cropland Reduction Programs

Application of Risk Assessment to Agricultural and Food Issues

Risk-Benefit Assessment of Antibiotics Use in Animals

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